UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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FEDERAL TRADE COMMISSION, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF OHIO, COMMONWEALTH OF PENNSYLVANIA, STATE OF ILLINOIS, STATE OF NORTH CAROLINA, and COMMONWEALTH OF VIRGINIA,

Plaintiffs,

v. 20 CV 706 (DLC)

MARTIN SHKRELI, et al.,

Defendants.

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New York, N.Y.
December 22, 2021
10:00 a.m.

Before: HON. DENISE COTE,
District Judge

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THE COURT: Counsel, I'm so sorry for the late start today. We will do whatever makes sense to counsel in terms of the schedule for lunch. When we get close to that time you will consult with each other and tell me what your preferences are. Thank you.

You may begin.

MR. MEIER: Good morning, your Honor. We will be dividing up the argument this morning. Real briefly, Lauren Peay will do part of the argument for the government. Maren Haneberg will also do part of the argument for the government. And then my colleague from the New York AG's office, Amy McFarlane. Yesterday your Honor asked a question about people appearing from New York or the states with witnesses. As it so happened, Ms. McFarlane and a number of other state attorneys who were going to be doing witnesses, those witnesses happened to be the ones, coincidentally, that fell out. But you will also be hearing from Ms. McFarlane. Ms. Peay will explain how we are going to divide that up. We are ready to go.

THE COURT: Perfect.

MS. PEAY: Good morning, your Honor. Lauren Peay from the Federal Trade Commission on behalf of plaintiffs.

Your Honor, the witnesses have testified, the evidence is in and had record is closed. The following facts are not seriously in dispute. Vyera's distribution restrictions prevented its distributors from selling Daraprim to generics.

Vyera's exclusive supply agreements with Fukuzyu and RL Fine prevented the two most viable suppliers from selling pyrimethamine API to generics. And, three, Vyera's data blocking agreements with two major distributors prevented them from reporting Daraprim sales data to IQVIA, obscuring the market opportunity for would be generic competitors.

What defendant, Mr. Shkreli, appears to be disputing is that despite his intentions, his plans, and his company's actions to thwart generic competition to Vyera's most important product, Daraprim, by any means possible and for as long as possible, he argues that none of it made any difference. And, even if he did, he wasn't responsible. The evidence overwhelmingly contradicts these defenses.

I will be joined today, as Mr. Meier said, by my colleagues, Maren Haneberg of the FTC and Amy McFarlane of the New York Attorney General's office. I will begin with an overview of the evidence plaintiffs have proffered that established the challenged anticompetitive conduct. I will then address one of the two overarching themes in Mr. Shkreli's defense, the no harm, no foul defense. This defense posits that even if the conduct occurred, it did not result in harm, or even if the conducted occurred and it did impede the generics, any harm is attributable to outside forces, like the FDA.

I will then turn it over to Ms. Haneberg, who will

address the second theme that has emerged in Mr. Shkreli's defense, the it wasn't me defense. And this defense posits that even if the conduct occurred and even if the generics were impeded, that was all Vyera. Mr. Shkreli was not involved.

Ms. McFarlane will then address the plaintiffs' request for injunctive and equitable monetary relief.

Martin Shkreli pioneered the anticompetitive business model at issue in this case, acquiring a small but essential drug with no patent protection, no competitors, but substantially increasing the price of the drug and then restricting distribution to prevent potential competitors from accessing that drug. You will hear much more about Mr. Shkreli from my colleague later, but Mr. Shkreli first implemented this model as CEO Retrophin, the first pharmaceutical company that he founded.

After being outed from Retrophin in September 2014, Mr. Shkreli founded Vyera to be able to continue profiting from his anticompetitive business model. As the founder, CEO, and largest shareholder of Vyera, in 2015, Mr. Shkreli selected Daraprim as the perfect drug to repeat his monopolization model.

With Mr. Shkreli at the helm, Mr. Vyera acquired Daraprim in August of 2015 and promptly raised the list price from $13.50 per tablet to a Shkreli-approved $750 per tablet, a hike of 4,000 percent.

I would like to turn now to plaintiffs' claim against the defendant. The FTC in seven states -- New York, California, Illinois, Ohio, Pennsylvania, North Carolina, and Virginia -- are challenging the actions that Vyera, with the participation of and control by Mr. Shkreli, took to prevent competition. Specifically, we are challenging this scheme which includes distribution restrictions, exclusive API agreements, and data-blocking agreements to prevent generic competition as monopoly maintenance under Sherman Act Section 2 theories, and we are challenging the distribution restrictions and API exclusivity agreements as unreasonable restraints of trade under Sherman Act Section 1 theories.

Now, a monopolization claim has two elements: The possession of monopoly power in a relevant market and the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product business acumen or historic accident. Plaintiffs have offered overwhelming evidence that defendant engaged in anticompetitive conduct and there is monopoly power over Daraprim.

Let's walk through the evidence of the anticompetitive conduct starting with the distribution restrictions. As Vyera's Tina Ghorban and Frank Della Fera testified here in court, the FDA requires any generic applicant to conduct bioequivalence testing comparing its product to samples of the

branded drug. To conduct this FDA mandated testing, the applicant is required to procure sufficient quantities of the branded product. The evidence has shown that Vyera carried out Mr. Shkreli's vision and that Vyera's distributors cannot sell Daraprim to generics because the distributors have agreed to sell only to specifically authorized customers or customer types. It is undisputed that generics are unable to purchase a RLD, or reference listed drug, from Vyera's distributors. These restrictions are spelled out in Vyera's agreements with its distribution partners as set forth in Government Exhibit 7003 in the demonstrative.

As Vyera's executive vice-president of commercial and operations, Anne Kirby testified by affidavit every single one of Vyera's written agreements with its distributors has restrictions on authorized customer types that can purchase Daraprim without Vyera's approval. Generics and their agents are not authorized customers, so no Vyera distributors can sell Daraprim to them without Vyera's express approval.

That express approval never comes. Generics requests to buy Daraprim follow typically a set pattern. Vyera's distributor receives a request and forwards it to Vyera's executives seeking approval, as shown here on the slide depicting GX-1139. The distributor seeks approval to sell Daraprim to the generic or its agent. Vyera's executives then tell the distributor, do not fulfill the request, and they

instructed the distributor to tell the generics or its agent to reach out to Vyera directly. There is no evidence that Vyera has approved a single request from generics or their intermediaries to purchase Daraprim for bioequivalence testing.

As we showed in Government Exhibit 7002, summary exhibit, the distributors benefited from the restrictions. Most Daraprim distributors get a certain percentage of Daraprim's list price, which Mr. Shkreli raised to $75,000 per bottle. One distributor gets a fee based on the volume sold. Regardless of the fee structure, lack of generic competition is a good thing for these distributors because it means that they can continue selling greater volumes of Daraprim at a higher price.

THE COURT: But even if the distributors didn't benefit financially, that doesn't interfere with your theory of the case. Am I right?

MS. PEAY: Yes, your Honor. That is correct.

As Ms. Ghorban, Vyera's former head of marketing and business analytics, testified, Mr. Shkreli and his business development team also were concerned that even with these class of trade restrictions, generics could acquire multiple bottles of Daraprim needed for FDA mandated studies. To mitigate this risk they implemented purchase limits on the number of bottles a customer could buy at a given time. Any customer seeking to buy a quantity exceeding the limit had to get Vyera's override.

Vyera has also aggressively monitored sales to ensure compliance with these agreements and has acted quickly to rectify any breaches. In fact, in September 2017, Mr. Kevin Mulleady ordered a full-out audit of Daraprim to know where every bottle of Daraprim we sold went to.

You have heard from defendant's counsel, and they have suggested that there is nothing unusual about class or trade restrictions, and that specialty distribution system can provide patient benefits.

There are two important responses to this. First, I'd like to make clear that plaintiffs have not offered evidence that specialty distribution in and of itself is anticompetitive. Rather, the anticompetitive conduct is the restrictions that prevent sales to generics. As Vyera's former chief commercial officer, Nancy Retzlaff, acknowledged, preventing generics from purchasing Daraprim for use in bioequivalence studies is not at all necessary for specialty distribution to function or for specialty pharmacies to provide services to patients. One has nothing to do with the other.

The second response is that the purpose of Vyera's distribution system is clear. We have heard it directly from Vyera's executives. Vyera's first general counsel, Howard Dorfman, testified the closed distribution system was part of Vyera's desire to block or certainly to delay entry of any generic. Former Vyera executive Tina Ghorban testified that

Martin Shkreli and the business development team discussed using closed distribution to make it harder for generics to acquire Daraprim. This system was designed, implemented, and executed to make it harder, much harder for generics to obtain samples of Daraprim needed for FDA approval.

Turning now to the exclusive API supply agreements. The evidence has also shown that exclusivity agreements sideline the two most viable producers of pyrimethamine API: Fukuzyu, and RL Fine. Pyrimethamine API is the key ingredient in Daraprim. Any pharmaceutical company seeking to make Daraprim or a generic version needs a source of pyrimethamine API.

Developing a pyrimethamine API manufacturing process can take many months. Mr. Bruno, plaintiffs' manufacturing expert, estimated at least 15 months and Vyera's Dr. Pelliccione estimated 12 to 18 months on the low end. For this reason drug companies prefer to use an API supplier that already has a manufacturing process, preferably one that has a DMF that is used in the market. Vyera's Dr. Pelliccione testified that it would help to work with a supplier who already knew how to make the API and who had a U.S. DMF.

Now, until the generic companies went out and developed pyrimethamine API manufacturing processes in partnership with their CMOs, the only two API suppliers with a manufacturing process were Fukuzyu and RL Fine. RL Fine itself

could not identify any other API suppliers, and an RL Fine sales executive testified that he has not come across anyone offering pyrimethamine API. And Mylan, one of the largest generic companies in the world, conducted a 15-month search to find a pyrimethamine API supplier but could only identify RL Fine.

THE COURT: Why do you think that's so? Why couldn't they identify Fukuzyu? Isn't that public record information?

MS. PEAY: Yes, your Honor. It is public record information. But by the time that they were searching, Fukuzyu had an exclusive agreement and was not entertaining offers to supply pyrimethamine API to other parties.

THE COURT: So it's not that they are the only two suppliers identified with the manufacturing process; it is the only supplier that reportedly was willing to sell.

MS. PEAY: Your Honor, they were the only two pyrimethamine API suppliers with a viable manufacturing process ready. Fukuzyu and RL Fine were the only ones. At the time when Mylan was searching for a supplier, they understood that Fukuzyu would not supply them.

THE COURT: Mylan identified Fukuzyu too.

MS. PEAY: They were aware of Fukuzyu too.

Let's turn first to Fukuzyu. The evidence has shown that Fukuzyu agreed to prevent generic companies from obtaining pyrimethamine API in exchange for the promise of additional

business. When Vyera acquired Daraprim, Fukuzyu was the pyrimethamine API supplier for the product on a nonexclusive basis. Obtaining an exclusive contract with Fukuzyu had long been Mr. Shkreli's goal. Even before purchasing Daraprim, Vyera contacted Fukuzyu to ask, can you sign up exclusivity with us?

After Mr. Shkreli was arrested, Vyera continued to pursue an exclusive supply agreement with Fukuzyu. On October 5, 2016, senior scientific executives from Vyera met with Fukuzyu in Japan. And on November 22, 2016, Vyera and Fukuzyu entered a supply agreement. Dr. Pelliccione told his subordinate, we got good news from Mikio in Japan overnight. Fukuzyu has accepted our agreement to provide pyrimethamine exclusively for us for human drugs and will not sell to generics manufacturers. That is a big sigh of relief for us.

THE COURT: There is this sort of gap in the record perhaps. Perhaps you can point me to what happened from, let's say, late 2015 to the fall of 2016 to get that exclusive supply agreement with Fukuzyu. I understand that there is record evidence that Mr. Shkreli had this goal to have an exclusive supply agreement with Fukuzyu from early on. But is there record evidence about what happened in that roughly nine-month gap to achieve that goal?

MS. PEAY: During that gap, when Vyera originally reached out to Fukuzyu, they didn't express interest in an

exclusive agreement at that time.

THE COURT: Yes. But, as I understand it, then in the fall of 2016, Vyera came back with an offer of a broad-based relationship that would involve not just pyrimethamine but other projects in the future potentially. So they came up with a strategy to make a play for Fukuzyu that might be more attractive, if I understand the record evidence.

My question is, do we have anything about that roughly nine-month gap? Why did it take nine months for Vyera to figure out a strategy to deal with Fukuzyu's initial response? Can you point me to anything, or not?

MS. PEAY: I don't have anything I can point you to specifically.

THE COURT: Thank you.

MS. PEAY: After Fukuzyu and Vyera entered a supply agreement on November 22, 2016 --

THE COURT: I think the agreement was January, wasn't it?

MS. PEAY: Ms. Guy, can you go back a slide.

In November 22, 2016, they accepted the agreement.

THE COURT: Yes. Sorry.

MS. PEAY: Sorry about that. It was the wrong wording.

Moving to the next slide, Ms. Guy, Vyera promised Fukuzyu additional business in order to compensate them for

that exclusive supply agreement. Dr. Salinas confirmed that the offer of additional business was intended to get them to sign the exclusive supply agreement. The evidence also shows that the Fukuzyu agreement does not actually guarantee supply. An exclusivity provision ensures that others will not purchase the API, but it does not ensure that you will receive the API.

As Mr. Bruno explained, if there was a surge in demand outside the United States, there is nothing in the Fukuzyu contract that would ensure that Vyera would receive pyrimethamine API from Fukuzyu. And also, to the extent that exclusivity provisions are used in the industry, they are designed to protect an investment, not guarantee supply. As Mr. Della Fera explained, Fera sought an exclusive contract with API 1 because we were paying for the development personally for our company. So the exclusive was to protect Fera's investment.

Turning now to the RL Fine supply agreement. With Fukuzyu locked up and eliminated as an API supply option for would be competitors, Mr. Shkreli and Vyera next turned their attention to another potential source of supply for the generics. Vyera began pursuing RL Fine in August 2017, when it received word that generics may be using RL Fine pyrimethamine API. And then on December 27, 2017, on behalf of Vyera, Mr. Mulleady executed two contracts with RL Fine.

THE COURT: Now, think there is some evidentiary

record that Vyera had two independent tipoffs of generic interest in RL Fine. I think there was a Frankfurt trade show and there was another conversation independent of that. Can you point me to anything else?

MS. PEAY: You are correct. There are two sources of information that tipped Vyera off that RL Fine may be supplying to generics. One was a presentation by Pennside Partners, and that identified that two generics were using RL Fine as supply. You are correct, there was a meeting in Frankfurt where RL Fine executives indeed confirmed that they were working with generics and that some of those generics may be ready to file an ANDA as soon as the end of that year.

I will walk through that in some more detail in a bit, but, yes, you are correct.

Under the agreement with RL Fine, Vyera is appointed the exclusive distributor. Vyera pays $1 million for a DMF that ultimately was never filed, and Vyera pays RL Fine 7.5 percent of Daraprim net revenues, regardless of whether RL Fine provides any API.

There is no evidence in the record that Vyera needed a backup supplier or that the RL Fine agreement ensured that Vyera would have a backup supplier. Vyera's scientific executives, like Dr. Pelliccione, did not even know that this contract existed and never considered getting a backup supplier, and there is no evidence in the record that Vyera

took any steps to add RL Fine to its NDA, which would allow it to be a backup supplier, or that it asked RL Fine to take the steps to be ready or to file a DMF.

THE COURT: I'm sorry. What is your point about Mr. Pelliccione?

MS. PEAY: Dr. Pelliccione, who has responsibility for scientific matters at Vyera, so, thus, would be knowledgeable about things like API supply, when he was deposed in this case, and this came out in his trial testimony as well, he had not been aware years later that there was this RL Fine contract, and he himself testified that he hadn't considered getting a backup supplier as one of the individuals at Vyera who would typically have responsibility for those.

THE COURT: There was some discussion about expiration dates of the API that Vyera had purchased, sort of the inventory API when it had purchased Daraprim. There was a question about, well, perhaps the fact you had all that API didn't mean it was readily available for you to use because even API has expiration dates. Is there any record evidence about the expiration dates of the API or what expiration dates there are for API, as opposed to the Daraprim once it's manufactured?

MS. PEAY: Your Honor, I can't point you to that record evidence right now, but I can note that to the extent that Vyera was seeking additional pyrimethamine API, if there

was a concern that their existing pyrimethamine API would expire, that would have been in the context of seeking the Fukuzyu -- supply from Fukuzyu, who actually did supply them with API. The RL Fine contract, which came later, never resulted in Vyera or RL Fine taking the steps to even allow RL Fine to even being able to supply the API.

Now, the amount that Vyera paid RL Fine, even though RL Fine supplied nothing to Vyera, is staggering. Each monthly royalty payment amounted to between 300,000 and 450,000. Ultimately, the evidence shows that Vyera terminated the agreement in October 2019, after paying RL Fine almost $9.5 million.

To put that figure in perspective, Vyera has paid Fukuzyu about $500,000 on all purchases of pyrimethamine API through March 2019. That means Vyera paid to RL Fine almost 19 times the amount for supplying nothing that it paid Fukuzyu for supplying all of its API needs.

The only possible conclusion from this evidence is that Vyera was paying RL Fine not to supply its competitors, which is in fact what Vyera's board minutes reflect. In the December 2017 board minutes, Government Exhibit 1490, Mr. Mulleady and Mr. Mithani brought the RL Fine agreement to the board. They explained that the rationale behind the collaboration with RL Fine is the diversification of the group's revenues stream from the potential market entry by

generics manufacturers and distributors. They do not mention backup supply or supply at all.

Mr. Mulleady and Mr. Mithani explained that addressing potential generic competitors are in the Vyera group's interests.

Turning now to the data blocking agreements, as former Vyera executive Tina Ghorban testified, IQVIA, formerly known as IMS, is a standard data source that companies and analysts use to understand the dynamics of markets.

Reaching back to his days at Retrophin, Mr. Shkreli knew that drug companies relied on IQVIA and other channel audits to forecast their potential revenue for launching drugs. We heard Ms. Ghorban's testimony that Mr. Shkreli knew that if sales appeared to go down, generic companies would have less interest in generic pyrimethamine development. So he used data blocking as part of his toolbox to discourage generic entry. Just three days after acquiring Daraprim, Vyera employees reached out to ICS and Walgreens, the only Daraprim distributors at the time, to inquire into blocking Daraprim data from IQVIA and other aggregators.

Ms. Guy, can you advance the slide.

Vyera immediately acted within three days of acquiring Daraprim to reach out to ICS and Walgreens to confirm that they weren't reporting.

Then, if you can move to the next slide, in September

2017, Vyera formalized its data blocking agreements with two of its main distributors, ASD and Cardinal, under which Vyera paid each a fee in exchange for the distributors agreement to not report its Daraprim sales data.

I'd like to turn now to monopoly power. The monopoly power question is whether Vyera can profitably sustain a small but significant price increase. As Professor Hemphill demonstrated, the shocking price increase here was very profitable for Vyera. Defendant's economic expert also agreed that Vyera's Daraprim price increase was profitable in every year since its acquisition of the product. It was not until generic entry that the profits began to drop.

It is undisputed that Vyera had a 100 percent share of FDA-approved pyrimethamine products from 2015 until generic entry in 2020. The Court has also heard about the significant barriers to entry into this market due to the FDA approval process for generics and Vyera's restrictions at issue.

Defendant's response to this has been to argue that TMP-SMX, or compounded pyrimethamine, can be used to treat toxoplasmosis in at least some circumstances. That is not the standard. Market definition looks at whether products restrain price. It is not enough that they can be used for the same purpose.

The evidence here shows that so many purchasers stuck with Daraprim, that its annual profits increased by tens of

millions of dollars. If these other products were close economic substitutes, no one would have paid a price increase like Vyera's. Nearly everyone would have switched.

But not only is defendant's argument about these other therapies legally misplaced, it is also contradicted by the evidence. Vyera's Dr. Salinas, a medical doctor, acknowledged that TMP-SMX is medically inferior to Daraprim, and Vyera's Dr. Pelliccione acknowledges that compounding in the large scale was not safe or appropriate. We also heard from plaintiffs' expert, Dr. Hardy, who explained that Daraprim has the strongest recommendation from the relevant clinical guidelines for treating active toxoplasmosis and that other therapies, like TMP-SMX, are not as good of substitutes. This is why people kept using Daraprim, even when the cost increased, by hundreds of dollars per tablet, despite the fact that TMP-SMX, or compounded pyrimethamine, cost only a small fraction of that.

I'd like to turn now to the first theme of defendant's defense here: No harm, no foul. Rather than fully engage with the overwhelming evidence of this conduct, Mr. Shkreli has focused on pointing the blame elsewhere.

The first way he has tried to shift the blame is by trying to argue that his vast scheme to prevent generic pyrimethamine competition actually had no effect. He would like the Court to believe that the FDA is to blame for the

delay in generic entry.

Your Honor may remember, when Mr. Shkreli's lawyer argued if only the FDA hadn't banned Ipca from importing API into the United States, Cerovene would have had its API supply source and Vyera's exclusive deals wouldn't have made any difference.

In addition to blaming the FDA, Mr. Shkreli blames the generics themselves. He argues that the generics didn't try hard enough to get Daraprim samples. They made bad -- he argues they made bad business decisions, and he argues that they tried to cut corners by seeking to purchase only three rather than five bottles of Daraprim RLD. But this defense does not fit with the evidence.

As we have heard from the generic companies themselves, they were all actively trying to develop, obtain approval, and launch generic versions of Daraprim. Mr. Shah testified that Cerovene's approach was, let's try to get the brand bottles, as many as we can as fast as we can. And Mr. Della Fera likewise testified that Fera wanted to be first to market for its generic pyrimethamine product.

But at every turn the generics were stimied by Mr. Shkreli's scheme. The classic closed distribution play prevented them from getting samples. The exclusive supply contracts prevented them from getting API. And for generics that were still in the initial stages of looking at making a

Daraprim product, after 2015, the data blocking made the market opportunity unclear.

THE COURT: So you may not be the lawyer to address this, so I apologize. It may be the last counsel for the plaintiffs. But I have tried to understand the defense argument about the generics not trying hard enough.

It seems to me that I'm not aware of a legal test that requires a competitor to use extraordinary efforts beyond anything normally seen in the business community or overcome every hurdle placed in their way. I have tried to understand the relevance, and I know defense counsel will address this, but just so plaintiffs' counsel can anticipate what I've been thinking about, I have tried to think of it instead as an argument about the calculation of damages perhaps.

Anyway, I am going to hear the relevance. You may not be the right lawyer to address this, that it's more an argument about they could have entered some months earlier if they had taken these additional steps, as opposed to really addressing the liability issue.

MS. PEAY: Your Honor, I agree with you that we are not aware of a standard that would require the generics to take every effort possible to get on the market. You are correct, Ms. McFarlane will be addressing the plaintiffs' case for disgorgement, for equitable monetary relief.

Let's move to the next slide, Ms. Guy.

I'd like to walk through the first roadblock then that Mr. Shkreli put up for the generics to overcome. This is the distribution restrictions. The evidence is clear that Mr. Shkreli's plan to prevent generics from accessing Daraprim impeded their entry and sent them scrambling for many months to try to obtain enough Daraprim to conduct the necessary testing.

Cerovene was hit particularly hard by these restrictions. In 2013, Cerovene had been able to purchase Daraprim samples from a local pharmacy. Back then, the pharmacy had been able to supply more than enough samples in about a day.

Fast forward to late December 2017, when Cerovene learns from the FDA that it needs to repeat its bioequivalence testing and now needs more bottles of Daraprim RLD. Cerovene had to go out and buy five bottles, all from the same manufacturing lot. This time around that local pharmacy could not supply any Daraprim RLD at all.

So what did Cerovene do? They reached out to various entities to try to source Daraprim RLD. This included hospitals, independent pharmacies, and sample procurement companies. Government Exhibit 3397 is a list of Cerovene's efforts. None were able to procure five bottles of Daraprim RLD.

Cerovene enlisted its marketing partner, Dr. Reddy's to help. Dr. Reddy's suggested prepaying $550,000 to Reliant

to acquire five bottles. But Vyera's aggressive monitoring allowed it to spring into action and promptly buy back Daraprim from Reliant that otherwise Reliant intended to sell to Dr. Reddy's.

On April 4, 2018, CentraState, a pharmacy affiliated with Reliant, ordered five bottles of Daraprim from ASD, Vyera's distributor. That same day Anne Kirby of Vyera noticed CentraState's five-bottle order of Daraprim where they had only previously purchased two bottles. She found this deviation suspicious and immediately contacted ASD to inquire about the order and was advised that ASD had already shipped the bottles. Ms. Kirby promptly flagged this transaction to Mr. Mulleady and Mr. Mithani. Mr. Mulleady then decided to buy back the five bottles from CentraState to avoid the risk of diversion to a generic.

Without much negotiation, Mr. Mulleady accepted CentraState's offer to sell the five bottles of Daraprim back to Vyera at $750,000, almost twice the original purchase price.

On April 6, 2018, Mr. Mulleady personally met with Satya Valiveti, the owner of CentraState, in a Starbucks parking lot to repurchase the five bottles of Daraprim. Following this buyback, Vyera instructed ASD to block CentraState's and its sister company, Reliant's, access to Daraprim. ASD implemented Vyera's request immediately.

As we have heard from Mr. Valiveti, because of Vyera's

buyback, Reliant and CentraState were unable to sell these five bottles of Daraprim to Dr. Reddy's or any other potential generic competitor. So but for that buyback, Cerovene would have had Daraprim RLD to conduct BE testing no later than April 2018.

Finally, after Cerovene spends 12 months, basically the entirety of 2018, to obtain Daraprim, Cerovene is able to cobble together three bottles from one source, but never the five they were seeking.

Defendant tries to shift blame away from its practices here and claim that Cerovene could have obtained the five bottles it needed back in early 2018 if only it had chosen to work with ProSupplier instead of Reliant. But there is no evidence in the record, none, that ProSupplier had five bottles of Daraprim RLD in early 2018 or at any other time.

In fact, there is no evidence in the record from ProSupplier at all. There are no documents from ProSupplier, which is based in Switzerland, and no one from ProSupplier was deposed. Defendants, instead, withdrew their Hague request for discovery from ProSupplier.

But we did hear from Cerovene and we did hear from Dr. Reddy's, both of whom testified live. And Mr. Shah and Mr. Mukhopadhyay testified that there were good reasons why they chose to work with Reliant. Mr. Shah indicated that because Reliant said they could get the RLD in two weeks versus

ProSupplier's estimate of four to six weeks, they went with Reliant. Time was of the essence. And Mr. Mukhopadhyay testified to the previous relationship with Reliant and how they were familiar with Reliant and also pointed to Reliant's promise that they could source the bottles sooner than ProSupplier.

We also heard from Mr. Valiveti of Reliant, who explained that actually, in 2018, ProSupplier had tried to source Daraprim from him, from Reliant. Of course we know that Cerovene and Dr. Reddy's were right to focus on Reliant because Reliant did successfully procure five bottles of Daraprim and was on the verge of selling those bottles to Cerovene until Vyera intervened.

THE COURT: Of course it was only successful because of a family relationship. It was sort of serendipitous. Maybe that's not the right word. But unusual.

MS. PEAY: Your Honor, are you referring to the family relationship between CentraState and Reliant?

THE COURT: Yes.

MS. PEAY: Yes, your Honor, that's correct. But, your Honor, Reliant was in the business of supplying RLD to various pharmaceutical companies. That was their regular business.

Like Cerovene, Fera also expended a great deal of effort trying acquire RLD but could not find any. Fera tried to get Daraprim from November 2016 through May of 2018. They

tried their normal supplier, a hospital, and they even went to Vyera itself through their CMO. Fera was able to get two bottles initially from Reliant, but was unable to get more from them, who by that time had been cut off by Vyera from access to Daraprim.

Without the required five bottles, Fera was forced to seek a waiver from the FDA, which was not granted until April 2019. The exclusive agreement with Fukuzyu also stimied the generics and wreaked havoc on their efforts to obtain approval and enter the market.

In 2015, when Cerovene had to find a new API supplier after its previous supplier Ipca had been banned from importing, it began negotiations with Fukuzyu. Cerovene recognized that Fukuzyu was its best option and even agreed to purchase much more API than it needed because Cerovene very much wanted to partner with Fukuzyu.

On October 4, 2016, while Vyera executives were in route to visit Fukuzyu's headquarters, Fukuzyu's CEO informed Cerovene that it would no longer be interested in dealing with Cerovene. Like Cerovene, Fera was stimied by Vyera's exclusive contract with Fukuzyu.

Fera contacted Fukuzyu in late 2017 seeking a supply relationship. Fukuzyu informed Fera, via a broker, it would not be able to supply pyrimethamine because they could not sell to a U.S. company for commercial use in humans. Fukuzyu's

message to Fera was verbatim. The language provided to them by Vyera's Dr. Pelliccione.

Instead, turned down by Fukuzyu, Fera was forced to work with an API supplier that had to develop a new pyrimethamine API manufacturing process. This further delayed Fera's entry onto the market.

Turning to RL Fine, the exclusive agreement with RL Fine also had significant consequences for generics.

(Continued on next page)

MS. PEAY: (Continuing) As Mr. Shah of Cerovene testified by affidavit, after Cerovene learned it could no longer use Fukuzyu, they turned to RL Fine.

Now, as I referred to earlier, your Honor, in August 10th of 2017, this is when Vyera receives a report from their competitive intelligence consultant, Pennside Partners. This report was the one that they identified two generics, Mylan and Sandoz, as purchasers of RL Fine pyrimethamine API. At this time, Mr. Mulleady, Mr. Mithani were running Vyera. Mr. Mulleady immediately forwarded the presentation to Mr. Shkreli.

Spurred on by Mr. Shkreli, Mr. Mithani and Mr. Mulleady reach out to RL Fine in August 2017 inquiring about pyrimethamine API.

Mr. Tilles, the then chairman of the Phoenixus board, meets with RL Fine executives at the end of August 2017 in Frankfurt. It was at this October 2017 meeting that RL Fine executives, as we discussed earlier, confirmed that the company was supporting several generic companies that would soon file pyrimethamine ANDAs. This information gets back to Mr. Shkreli, who then texted Mr. Mulleady from his contraband phone: "It's Shkreli. Trying to get in touch with you urgently. Hearing pyri ANDA approval in December 2017."

The evidence then shows that Mr. Mulleady and Mr. Mithani pushed forward with negotiations with RL Fine in

November, ultimately leading to the signing of the exclusive agreement that I referenced earlier on December 27, 2017.

Now, on the first day of trial, Mr. Shkreli's lawyer tried to imply that Vyera's RL Fine deal could not possibly have affected RL Fine's decision not to work with the generic companies because the agreement wasn't signed until December 27, 2017, which was nearly a month after RL Fine informed Cerovene that it would no longer supply it with pyrimethamine API.

But the full-time line paints a very different picture. On November 2nd, 2017, Mr. Mulleady reaches out to RL Fine and offers 1.25 million per year to finalize their, quote, exclusive agreement.

On November 25, 2017, Mr. Mulleady and RL Fine then reach an informal agreement. This is just five days before RL Fine cuts off Cerovene on November 30, 2017. Then, moving forward, two years later, when Vyera ends the RL Fine contract, RL Fine was back supplying Cerovene within a couple of months of the termination of that contract.

It is clear from the evidence that the restrictions Mr. Shkreli and Vyera imposed, they resulted in incredible roadblocks that stymied the generics in so many ways. It's also clear that despite these roadblocks, the generics worked tirelessly for years to try to get on the market. It's clear that to suggest that outside forces may have played a role in

the generic difficulties getting to market is to ignore the plain evidence that the root cause of the generics' difficulties were the defendant's actions. When you consider all this evidence, it is amazing that these companies persisted and that generic entry has occurred at all so far.

Now, your Honor, my colleague, Ms. Haneberg, is prepared to address Mr. Shkreli's second overarching defense.

THE COURT: Thank you.

MS. HANEBERG: Thank you, your Honor.

Good morning, your Honor. May it please the Court, Maren Haneberg, from the FTC and on behalf of all plaintiffs.

I will now address the second overarching defense we have heard from Mr. Shkreli, and that is, even if there were antitrust violations, it wasn't his conduct that was the root of those violations. This is despite the fact that he masterminded the scheme at issue.

Mr. Shkreli meets the individual liability standard for an antitrust violation. He had direct participation in those violations and the authority to control Vyera.

Mr. Shkreli need not always be an employee of Vyera to be held individually liable. Mr. Shkreli had, and has, the authority to control the corporation because he is the controlling shareholder; in other words, he owns Vyera. And even if Shkreli had ceased involvement after setting the scheme in motion, he is still liable for the continuance of that

conduct because it did not materially change after his formal tenure at Vyera ended.

According to Mr. Shkreli's own written testimony, having only worked at hedge funds since graduating college in 2004, and with zero actual pharmaceutical industry experience, Mr. Shkreli formed the drug company that would become Retrophin in late 2010. There, as Ms. Peay earlier explained, he pioneered the anticompetitive business strategy that he would later apply to Daraprim. That is acquiring a small, but essential drug with no patent protection and no competitors, substantially increasing the price of the drug, and then restricting the distribution to prevent potential competitors from accessing the drug for FDA-mandated bioequivalence studies.

Mr. Shkreli acknowledges that while he was CEO, Retrophin acquired or licensed to such drugs, Chenodal and Thiola, and raised their prices to, quote, generate revenue.

Ms. Guy, the slide is up? Oh, thank you.

Mr. Shkreli's plan to protect these price hikes through closed distribution to prevent generic access was not a secret. In public Retrophin investor calls, Mr. Shkreli proudly boasted of his distribution plan. In a February 2014 investor transcript, he explained: "Chenodal will continue to be distributed through Centra, a special pharmacy. This unique distribution system does not allow for generics to access

product and to conduct bioequivalence studies as required against the reference listed drug, and the filings are almost impossible unless a generic company illegally penetrates the specialty pharmacy distribution."

He goes on to explain, "I think we have a really good handle on making sure that generics won't enter or gain access to our product, and that's a key feature. To our knowledge, as I mentioned, this model has protected virtually every single company that has it from generic competition."

In another investor call in May of 2014, he bluntly stated: "Our distribution strategy for rare diseases is closed distribution. The closed distribution system allows for us to control the release of our product. We do not sell Retrophin products to generic companies. The specialty pharmacy distribution model takes the AB substitutable rating that generics rely on and neuters it."

Again, these are Mr. Shkreli's public statements regarding his reasons for utilizing closed distribution.

While at Retrophin, Mr. Shkreli also tried to acquire and apply the strategy to Cuprime and Syprine, other drugs used to treat another life-threatening disease. Though ultimately unsuccessful in acquiring the drugs, Mr. Shkreli had planned to increase the price of those lifesaving drugs for which there was no alternative therapy by 10 to 30 times and closing the drugs' distribution, so, quote, "Generics become unable to

source the product for their bioequivalence study."

As Ms. Peay explained, upon Mr. Shkreli's ouster from Retrophin for alleged misconduct, Mr. Shkreli founded Vyera with the intent of replicating the same anticompetitive business strategy that he had successfully implemented at Retrophin. As bluntly put to early potential investors, exclusivity, meaning closed distribution, creates a barrier and pricing power.

And as Mr. Shkreli himself testified, Vyera's business development group focused on identifying lifesaving drugs in which Vyera should invest. That would be to add shareholder value through licensing or acquiring these drugs and then, quote, "improving distribution networks."

Vyera's first target under Mr. Shkreli's direction was Biltricide, another old gold standard treatment for a parasitic infection that had no patent protection. Mr. Shkreli aimed to increase the price of treatment, which was comprised of a total of six pills, from under $100 to over $100,000, again, using closed distribution to curb generic risk. Mr. Shkreli actually tried to recruit Fera Pharmaceuticals' CEO, Frank Della Fera, into investing into his Biltricide scheme. Mr. Della Fera was perplexed as to how he planned to turn this old low revenue drug into a blockbuster. As Mr. Della Fera testified, "I assumed that he knew of some new indication for Biltricide, but Mr. Shkreli never indicated that was his plan. Instead, he

simply mentioned that he planned to raise the price and put the drug into a closed distribution system to deter generic entry."

When Mr. Shkreli and Vyera failed to close the deal on Biltricide, they set their sites on Daraprim. As Mr. Shkreli explained to one investor prior to closing the acquisition, "Despite Daraprim having no orphan or patent exclusivity left, I feel very good that there are no incoming generics, and now that it is closed distribution, there will not be any going forward. Of course, even if we get three years, it is a great payout." And it was Mr. Shkreli himself who executed the Daraprim asset purchase agreement on behalf of Vyera.

Through the live and designated deposition or investigational hearing testimony of five of Mr. Shkreli's former employees, we have heard repeatedly that the plan to utilize closed distribution was intended to block generic entry and that the plan was originated and driven by Mr. Shkreli.

Michael Smith, who worked both in business development with Mr. Shkreli at both Retrophin and Vyera, testified via designation that it was Mr. Shkreli who came up with that thesis.

As Ms. Peay cited earlier, Mr. Dorfman, Vyera's prior general counsel, he understood the closed distribution system was part of Vyera's desire to block or certainly to delay entry of any generic.

Another former general counsel of Vyera, Eve

Costopoulos, testified that it was her personal understanding that there was a strategy to control the drug so that -- and to protect the drug from generics for as long as possible, meaning protect a generic or potential generic manufacturer from obtaining the drug so that they could then develop a generic form of the drug.

And as Ms. Peay also pointed out earlier, Ms. Ghorban, Vyera's then head of marketing and business analytics, it was also her understanding that the strategy of using closed distribution was to prevent generic entry.

She also testified that a generic launch would decimate Vyera's revenue -- Daraprim revenues on which it was dependent.

Finally, Nancy Retzlaff, Vyera's chief commercial officer, also testified via deposition that being a small company, Mr. Shkreli was intimately involved with ultimate responsibility for setting the strategy.

And it was Mr. Shkreli's belief that to the extent that a generic company was challenged to get samples of the product, that would impede their ability to conduct a bioequivalence -- to get the product sufficient to conduct a bioequivalence study. That was the purpose of closed distribution.

As the founder and CEO of Vyera, Mr. Shkreli made all of the decisions. He made the decision to acquire Daraprim at

a premium price of $55 million, despite having only $4 million in annual sales, and no patent or regulatory protection, knowing that he would profit from his anticompetitive strategy.

As Mr. Shkreli explained, "It was clear to me that Daraprim was significantly undervalued and that if Vyera could acquire the drug at the right price, the acquisition made sense."

And Mr. Shkreli made the decision to restrict the distribution of Daraprim to prevent generics from accessing the RLD they would need for FDA-mandated bioequivalence testing.

And it was Mr. Shkreli who made the decision to raise the price of Daraprim from $17.50 per tablet to $750 per tablet. Even after the public backlash to such an outrageous price increase to an essential lifesaving drug, Mr. Shkreli publicly stated that his only regret was not raising the price even higher.

Asked by an audience member at a healthcare summit hosted by Forbes what he would do differently if he could go back in time, he replied, "I probably would have raised prices higher as that is probably what I should have done. I could have raised it higher and made more profits for our shareholders, which is my primary duty."

It should be noted that Mr. Shkreli is, and always has been, Phoenixus' largest shareholder.

To this day, Mr. Shkreli defends his conducted: "I

accept full responsibility for the price increase, which I still believe was the right decision for the company and the patient community."

In sum, it was Mr. Shkreli who made all of the decisions. As Mr. Tilles, who took over as interim CEO when Mr. Shkreli stepped down, testified, it was not the senior leadership team making all the important management decisions, it was Martin Shkreli.

And in Martin Shkreli's own words: "I was the boss of the entire company."

Once Vyera had acquired the Daraprim rights, Mr. Shkreli's marching orders were to ensure Daraprim was moved into closed distribution as swiftly as possible in order to minimize exposure, meaning minimize exposure to generic competitors being able to access Daraprim.

Under Mr. Shkreli's leadership, Vyera worked to further restrict the distribution of Daraprim. As Mr. Dorfman testified at trial, the distribution system was generally made even more restrictive, identifying with a desire to identify with particularity every -- to the extent possible, every pill that was being distributed by the company.

Vyera also immediately focused on purchase limits, keeping Shkreli apprised of any developments, and Mr. Shkreli also closely monitored the Daraprim sales data. Even after leaving -- having formally left the company — I'm sorry — he

was still a board member. He carefully tracked the commercial sales of Daraprim in order to make sure that our, quote, "distribution wasn't penetrated by a generic."

As my colleague, Ms. Peay, discussed earlier, with Vyera dependent on sales to generate revenue, Mr. Shkreli and Vyera were not content to solely rely on closed distribution to prevent generic entry. Mr. Shkreli also set the course to do everything possible to keep generics from accessing the most viable sources of API.

As Mr. Smith testified, it was Mr. Shkreli's desire to enter an exclusivity agreement with Fukuzyu. That idea originated with Mr. Shkreli.

Mr. Shkreli first had Mr. Smith -- asked Mr. Smith to contact Fukuzyu in May of 2015, just as negotiations with Impax to acquire the rights were beginning.

And in June -- early June 2015, a Fukuzyu sales representative responded to Vyera's inquiry, and this is a follow-up to an email Ms. Peay showed earlier — this is GX 1200 -- 1209. The sales representative responded to Vyera's inquiry as follows:

"Do you have any exclusive agreements to supply pyrimethamine in the United States?

"Yes, we do.

"Can you sell us pyrimethamine?

"Sorry, we can't.

"Can you sign up exclusivity with us?

"Sorry, we can't."

When Mr. Smith forwarded this exchange to Mr. Shkreli, Mr. Shkreli replied: "Hopefully, it is Impax, because then it would be unlikely a generic is out there. Only one other DMF, which was Ipca, and they can't do it. I think DMFs are highly preferred by FDA and arguably even required."

As Mr. Tilles explained, even if Mr. Shkreli wasn't physically present in Japan for the execution of the agreement, exclusivity with Fukuzyu was Mr. Shkreli's idea and intention, it was something he wanted, and it happened.

Data blocking was also key to Mr. Shkreli's plan to prevent generic competition to Daraprim. Again, even prior to the acquisition, Mr. Shkreli sought to prevent sales data from being reported to IMS, now known as IQVIA, and other third-party data aggregators in order to mask the true size of the Daraprim market opportunity. As Ms. Retzlaff, the former chief operating officer, explained, Mr. Shkreli believed that by limiting data to generic manufacturers, that would limit or impede their ability to assess the size of the market opportunity.

Vyera's efforts to get ICS and Walgreens not to report sales to IQVIA, again when Mr. Shkreli was still CEO, and in May 2016, even after having formally departed from Vyera, Mr. Shkreli wrote Mr. Tilles, Mr. Crutcher, and Ms. Retzlaff

demanding to know how are there still so many Daraprim bottles getting through to IMS.

It is clear that Mr. Shkreli's official exit from the company in February 2016 did not stop his involvement in the anticompetitive scheme. Mr. Shkreli has regularly used his shareholder voting power, or the threat thereof, to control the management of Vyera.

Mr. Tilles who, again, took over as interim CEO upon Mr. Shkreli's departure, understood Mr. Shkreli to be exerting, quote, shadow control over the company.

When Mr. Shkreli grew unhappy with those he had left in charge, he called an extraordinary general meeting, known as an EGM, something only he has the sufficient shareholder power to do, and installed a new board comprised of his thoroughly unqualified cronies.

As Mr. Shkreli himself testified via affidavit, "In 2016, I was not satisfied that Vyera was moving in the right direction and became concerned about the future of the company, which at the time was my largest investment. I was particularly frustrated by the way that Ron Tilles, who had been named interim CEO, was managing Vyera. As a result, I organized a proxy fight to remove members of the board of directors of Phoenixus that I didn't think were doing a good job, including Mr. Tilles. The proxy fight was successful, and my slate of directors, which included Kevin Mulleady and Akeel

Mithani, was elected."

THE COURT: So does the record reflect anything that would indicate that Mr. Tilles or those in charge before their ouster were doing anything to unwind the anticompetitive conduct you've identified?

MS. HANEBERG: Your Honor, no. Quite to the contrary, they were pursuing Mr. Shkreli's scheme throughout that time period.

THE COURT: So we have this statement from Mr. Shkreli as to his unhappiness, but do the plaintiffs have a view as to what the record might show as to the source of that unhappiness?

MS. HANEBERG: I believe that -- your Honor, I believe it is a variety of issues, and some of it included personal issues between Mr. Tilles and Mr. Shkreli, and that ultimately resulted in a dissolution of the relationship.

Mr. Tilles was actually fired as CEO before the formal EGM took place to remove him, but I don't believe that there was any disagreement over whether he was actually pursuing the anticompetitive business strategy that Mr. Shkreli had set in motion.

Prior to the EGM, the then board of directors implored shareholders not to elect Mr. Shkreli's proposed slate for three key reasons --

THE COURT: I'm sorry?

MS. HANEBERG: I'm sorry.

Prior to the EGM, the then board of directors implored shareholders not to elect Mr. Shkreli's proposed slate for three key reasons:

The first was an utter lack of transparency. Mr. Shkreli provided no rationale behind his proposals. He initiated litigation against the company, and his communications with Turing's group staff and other shareholders was vitriolic and accusatory.

They were also extremely concerned by undue involvement of Mr. Shkreli. As they explained to shareholders, over the past year, Turing has faced substantial inquiries and mistrust from consultants, auditors, banks, insurers, regulatory authorities, and even potential customers due to Martin Shkreli's actual and perceived involvement in the company, first as the CEO and now as a shareholder.

The then board found Mr. Shkreli's proposed slate to be, quote, "woefully inadequate." The board, quote, "believes that in case of their election, many third parties, including regulatory authorities, will likely deem the newly elected board members to be serving merely as strawmen acting on Mr. Shkreli's behalf."

Finally, the board found that there was an utter lack of qualifications, and conflicts of interest were rife. Board of directors did not believe that the candidates proposed by

Mr. Shkreli had the independence, nor the finance, biotech, or pharma or leadership experience required for membership on a pharmaceutical board.

Despite these serious concerns, Mr. Shkreli used his shareholder power to elect his chosen slate in June 2017. After the vote, it became clear, in the testimony of Mr. Tilles, that Shkreli just wanted absolute control of the votes by installing all his cronies.

Within 24 hours of their election, Shkreli's newly elected board fired Dr. Salinas as CEO and Eve Costopoulos as general counsel. As Dr. Salinas testified at trial, Mr. Shkreli was successful in getting his slate of directors involved despite their lack of qualifications. In the end, Dr. Salinas was out and Mr. Shkreli's people were in.

Key among the five newly elected board members were Kevin Mulleady and Akeel Mithani, who quickly became the sole members of a newly formed executive committee, which was to perform the executive functions and take over the tasks of senior management, meaning chief executive officer, chief financial officer, chief commercial officer, and chief legal officer.

Mr. Mulleady had worked for Shkreli at his hedge funds, Retrophin, other Shkreli startups, and Vyera at its founding. After Mr. Shkreli's formal departure, Mr. Tilles had fired Mr. Mulleady for his lack of abilities.

Mr. Mithani was a recent college graduate and another close Shkreli associate, who admitted at his deposition that he did not think he had the qualifications to join the board at that time.

Mr. Mulleady would go on to assume the role of CEO and chairman of the board. Mr. Mithani became senior vice president of business development.

Mr. Shkreli himself has referred to this board as the, quote, "Martin and Kevin board." As Mr. Shkreli said in a prison phone call to Mr. Mulleady, "Being on the board of Phoenixus means, you know, you're on the Martin and Kevin board. Between the two of us, we control more than 50 percent, so that's the first thing you know off the rip."

Mr. Shkreli went on to explain, "Like the first thing, it's like Facebook, you can't go in there and tell Zuckerberg what to do. You know, you can give him advice, you know, it's just he happens to own the thing, and that's the way it is."

As Mr. Mulleady testified at trial, Mr. Shkreli in this passage was likening himself to Mark Zuckerberg of Facebook.

Central to Mr. Shkreli's continued control of Vyera is his EGM power, that is, his ability as the largest shareholder to call an extraordinary general meeting to remove and/or install his chosen directors. He has repeatedly flexed this power.

In another call from prison, he explained: "I'm ready to hold Averill — as in Averill Powers, the CEO — accountable, Akeel Mithani accountable, and you, Kevin Mulleady, accountable if something doesn't get done." He continued that: "I have EGM power. I mean, I have no problem firing everybody, to be frank, if you guys can't figure it out."

Mr. Shkreli has fought tooth and nail to ensure that his anticompetitive strategy not only remained in place, but actually expanded in scope even after his imprisonment in September of 2017.

In terms of distribution, Mr. Shkreli urged the tightening, further tightening, of the supply chain. In a phone call to Mr. Mithani, Mr. Shkreli instructed Mithani that Vyera should be, quote, "doing everything possible to prevent a generic company from obtaining a sample of Daraprim, as this would mean making Daraprim a $600 million asset in perpetuity."

Mr. Shkreli instructed Mulleady on how to deal with Mr. Della Fera when they suspected that Fera might be approaching generic entry. Mr. Shkreli explained: "The number one thing I would do is just really carefully screen every doctor that you know, even if it drops sales a little bit. It's a good -- you know, really make sure he's not getting his hands on anything."

And in terms of API, it was Mr. Shkreli who crafted some of the original outreach to RL Fine. If you compare

GX 1104 to GX 1129, it is clear that Mr. Shkreli crafted one of the original emails to reach out to RL Fine, which Mr. Mithani simply copied and pasted and sent on to RL Fine.

Mr. Shkreli was integrally involved in Vyera's RL Fine exclusivity effort.

Ultimately, Mr. Shkreli grew dissatisfied with Mr. Mulleady and called yet another EGM to remove Mr. Mulleady from the board, and Mr. Mulleady was, in fact, voted off the board at an EGM in December of 2020.

But Mr. Shkreli's reasons for dropping Mr. Mulleady from the board indicate that Mr. Mulleady never should have been elected to the board in the first place, as he, quote, "lacked pharmaceutical knowledge base."

As Mr. Shkreli testified at his deposition: "One of the things I have implored Mulleady to do over at least the last several years, but certainly in the last 12 months, over and over again, is to really try to focus and learn as much as he can about the pharmaceutical industry, where I think there are topics — not all topics, but some topics — he is fairly deficient in that I think he owes it to himself and to those around him in his career to work on."

He continued: "I wanted him to sort of increase his knowledge base in pharmaceuticals. This was not -- pharmaceuticals is not an easy business to understand, and there would be many moments in time where I felt Kevin

demonstrated his lack of understanding and lack of knowledge and fact-specific knowledge, especially in pharmaceuticals."

Having no pharmaceutical knowledge base, one can only infer that Mr. Shkreli elected Mr. Mulleady to run Vyera simply because of his close ties to Mr. Shkreli.

Shkreli believes, and regularly demonstrates, that the power to hire and fire falls to him --

THE COURT: Let's just pause there.

MS. HANEBERG: Yes.

THE COURT: With this removal of Mr. Mulleady, again, I'm not aware of any record evidence that before his removal, Mr. Mulleady, or those he was working with within Vyera, were doing anything to unwind the anticompetitive practices to which the plaintiffs are pointing, that the removal had to do with other reasons.

Is that your understanding of what the record evidence is as well?

MS. HANEBERG: Your Honor, I agree, the record evidence shows that the removal of Mr. Mulleady was not due to any dampening of anticompetitive efforts; in fact, Mr. Mulleady spearheaded numerous efforts to further restrict the ability of generics to get on the market. I will just note two points, which is that, after significant questioning by the FTC, Vyera did pay RL Fine to terminate its exclusivity agreement, and there were board minutes reflecting a very different reason for

the RL Fine agreement than what had happened when they actually entered into it.

Second, I will note that after we filed the complaint in this action, I believe Vyera terminated its data blocking provisions with its distributors. I believe both of those were -- I think the record would indicate that both of those were in response to investigation or action by the FTC and the state attorneys general, but I did want to be fully candid that those two things did happen under Mr. Mulleady's tenure.

THE COURT: Thank you.

MS. HANEBERG: Mr. Shkreli believes and demonstrates that the power to hire and fire falls to him, as the largest shareholder.

He explained in his deposition: "As the largest shareholder, at least in my experience, a lot of those sorts of decisions" — referring to removing Mr. Powers -- from potentially removing Mr. Powers from the company — "they ended up going to the largest shareholder."

The evidence shows, your Honor, that Mr. Shkreli meets the standard for individual antitrust liability. He masterminded the scheme. He set the scheme in motion. He had, and continues to have, control over the corporation through his ability to hire and fire.

And even if any of Mr. Shkreli's involvement had ceased, he would still be liable for the continuance because

his scheme did not materially change after his formal tenure at Vyera ended.

Your Honor, I will now turn over to my colleague, Amy McFarlane, from The New York Attorney General's Office, to discuss remedy.

THE COURT: Before we do that, just one second here, does anyone need a break?

Not seeing any desire for that, great, go ahead.

MS. McFARLANE: Good morning, your Honor. And may it please the Court, I'm Amy McFarland, from the New York State Attorney General's Office. I'm also speaking today on behalf of the government plaintiffs.

I'd like to briefly address our authority to seek injunctive relief and the state's authority to seek equitable monetary relief in this case.

Your Honor, ever since New York initiated the Daraprim investigation in 2015, we and the other plaintiff states have worked closely with our sister enforcers at the Federal Trade Commission to address the conduct that allowed defendant, in 2015, to implement a 4,000 percent increase in the price of Daraprim, a lifesaving drug, and to unlawfully maintain that 4,000 percent increase by engaging in anticompetitive practices.

The evidence clearly shows that Martin Shkreli, through the company that he controlled, directed and

participated in a comprehensive scheme to prevent generic competition for Daraprim to protect his massive price hike. This scheme, designed to maintain a monopoly on Daraprim, violated the antitrust laws.

As your Honor knows from our papers, the FTC and the states, particularly New York, have strong independent federal and state law bases for the equitable relief sought in this case. Here, I'll be touching on those legal bases and on the appropriateness of three aspects of that relief:

First, permanently banning Mr. Shkreli from working in the pharmaceutical industry, consulting in the pharmaceutical industry, or having any meaningful ownership interest in a pharmaceutical company.

Second, the disgorgement of unjust gains.

And, third, the application of joint and several liability in relation to the disgorgement of unjust gains.

So, first, with respect to an injunction: The FTC act, the Clayton Act, and state law authorize the plaintiffs to seek strong injunctive relief, including industry bans against individuals when equity demands it.

The New York Attorney General has the ability to seek broad equitable relief under Section 63.12 of the New York executive law, which is a remedial statute, not a penal statute.

Through Section 63.12, the Attorney General has

secured lifetime bans against individuals who repeatedly or persistently violate the law. In litigated cases, our state courts have exercised their equitable discretion to issue industry bans against lawbreakers in a variety of industries.

As noted in our papers, the Attorney General has secured injunctions banning individuals from everything from the business of equipment leasing, to the business of mortgage foreclosure consultation, to the business of selling, breeding, or training of dogs.

These industry bans were not time limited, and they did not provide carve-outs for certain activities. They were permanent, plenary injunctions.

Here, federal law and New York law should be used to ban Martin Shkreli from the pharmaceutical industry for life.

To be sure, banning an individual from working in an industry is a serious remedy, but where egregious conduct demands it, it is the proper remedy. And, here, the defendant's conduct warrants a permanent industry ban. He has repeatedly undertaken to profit by grossly distorting competition in pharmaceutical markets and will do it again unless he is banned from the industry.

Mr. Shkreli's chose not to attend this trial and offer his testimony live, but we know from the --

THE COURT: You have to slow down --

MS. McFARLANE: Okay.

THE COURT: -- so that the reporter can catch every word you say and so I can catch every word you say.

MS. McFARLANE: Thank you very much, your Honor, and I apologize.

THE COURT: Thank you.

MS. McFARLANE: Mr. Shkreli chose not to attend this trial and offer his testimony live, but we know, from the many facts in evidence at this trial, that Mr. Shkreli participated in, and directed, the illegal scheme at issue in this case.

While at his prior pharmaceutical company, Retrophin, Mr. Shkreli pioneered his strategy of restricting distribution to foreclose generic -- to foreclose potential generic competitors from getting the drug samples necessary to conduct FDA testing for generic approval.

At Retrophin, he bragged to investors that putting drugs into closed distribution has protected virtually every single company that has it from generic competition. He used this strategy at Retrophin to protect price increases after he raised the price of Chenodal from $100,000 to $515,000 a year, and raised the price of Thiola from $4,000 to $80,000 per year.

Then Mr. Shkreli started Vyera. His business development team that had implemented his strategies at Retrophin followed him to Vyera. Vyera, under Mr. Shkreli's control, acquired Daraprim from Impax. As we've heard from Dr. Hardy, Daraprim is used to treat central nervous system

toxoplasmosis, a disease that most frequently afflicts immunocompromised individuals, such as those with uncontrolled HIV.

Under the control of Shkreli, Vyera acquired Daraprim and immediately increased the price 4,000 percent, a price that we've heard former Vyera executive, Dr. Salinas, call excessive, crazy, irresponsible, and the poster child of everything that is considered wrong about the pharmaceutical industry.

Dr. Salinas testified that this kind of massive price hike was Mr. Shkreli's business model. To be able to protect and maintain this grossly excessive price, Vyera imposed restrictions on API suppliers, distributorships, and information flows. Mr. Shkreli, the largest shareholder of Vyera's parent corporation, directed and participated in the scheme continuously from 2015 to the present, even from prison. Because of that conduct, generic entry was impeded, and Vyera was able to force patients to pay its exorbitant price for Daraprim.

As Dr. Hardy testified, and as we've seen in emails from Massachusetts General Hospital, Shkreli's scheme to inflate the price of Daraprim forced physicians and vulnerable patients in life-threatening situations to turn to second-best treatments. Mr. Shkreli has testified that he contemplates some sort of return to the pharmaceutical industry when he is

released from prison. This must not happen.

Equity demands that Mr. Shkreli be permanently banned from the pharmaceutical industry. A conduct-specific injunction that would allow Mr. Shkreli's continued participation in the pharmaceutical industry would be more difficult to monitor and enforce and would not be sufficient to protect consumers.

We ask the Court to use the federal and New York State law to issue the strong injunctive relief to ensure that Mr. Shkreli cannot repeat this or any other kind of reprehensible conduct in the pharmaceutical industry when he is released from prison.

Banning Mr. Shkreli from the pharmaceutical industry would also send a powerful signal to corporate executives in the pharmaceutical industry that they cannot engage in illegal schemes to reap monopoly profits at the expense of vulnerable patients.

Turning now to the equitable monetary relief, sought by the state plaintiffs in this case. As your Honor knows, following the Supreme Court's decision in the AMG case, monetary relief here is the unique province of the states.

Your Honor has already found in this case that the plaintiff states have parens patriae standing to bring this action for equitable relief. Your Honor determined, in your partial summary judgment ruling, that the New York Attorney

General has the authority to seek disgorgement of defendant's net profits. Your Honor also ruled that New York has authority to seek disgorgement of unjust gains from the defendant based on the entirety of U.S. sales of Daraprim because the locus of the wrongful activity was in New York State.

Case law counsels that the district court has broad discretion in calculating the amount to be disgorged. In the Second Circuit, *FTC v. Bronson* provides the guiding principles for calculation of disgorgement. *Bronson* tells us that the plaintiffs bear the burden of showing that the disgorgement calculation reasonably approximated the amount of defendants' unjust gain.

(Continued on next page)

MS. McFARLANE: *Bronson* specifies that this should be the calculation of the profits resulting from the unlawful conduct less any direct costs incurred by the defendant. If plaintiffs make this showing, the burden then shifts to the defendants to show that the figures were inaccurate.

SEC v. First Jersey Securities counsels that any risk of uncertainty in calculating disgorgement should fall on the wrongdoer whose illegal conduct created the uncertainty.

Here, Professor Hemphill has calculated the amount of unjust gain resulting from the illegal activity. He has reasonably approximated that unjust gain to be $64.6 million. As we heard from Professor Hemphill, he was assigned to construct a model that calculates the amount of excess profits under a variety of counterfeit factual scenarios that reflect the likely timing and extent of entry, absent Vyera's unlawful conduct. In order to make this calculation, Professor Hemphill undertook four steps, each of which I will briefly address.

First, Professor Hemphill calculated Vyera's net Daraprim revenue in the actual world over the relevant period, October 2018, when Professor Hemphill assumed the first generic would have entered, through December 2020. This is a relatively straightforward calculation.

Revenues for the relevant period, less discounts, rebates, and chargebacks paid to distributors, purchasers and payors, Professor Hemphill calculates this figure to be $130.6

million. This is actually a conservative estimate, since he only considered data through the end of 2020, even though Shkreli's scheme continued to yield unjust gains after that date.

Second, he calculated Vyera's revenue in the counterfactual but-for world associated with a number of different scenarios for generic and authorized generic entry.

Now, one issue that is always central to the construction of the counterfactual is whether the assumptions that were made to construct the counterfactual were reasonable.

Here, Professor Hemphill has said that he relied on the testimony and documents from the generic drug makers, Cerovene and Fera. We have heard from the generic manufacturers, Cerovene and Fera, that they were delayed from entering the market because of restraints on their ability to source API and obtain samples for FDA testing. This is despite the fact that they doggedly pursued every avenue to overcome the roadblocks erected by Mr. Shkreli and Vyera.

We heard from Manish Shah, the president of Cerovene. Mr. Shah testified that in a world where Fukuzyu agreed to supply Cerovene with API in October 2016, and in a world where Cerovene had no trouble sourcing Daraprim RLD, Cerovene could have filed its amended ANDA in February 2017. Mr. Shah told us that if Cerovene were using Fukuzyu API, the FDA likely would have approved the ANDA in six months, in August of 2017.

Cerovene then would have completed validation batches and would have entered in November 2017. This is actually earlier than Professor Hemphill had anticipated in the very conservative but-for world that he constructed.

We also heard from Frank Della Fera, the CEO of Fera. Mr. Della Fera said that in a normal world, without the restraints imposed by the defendant, he would have expected to source API from Fukuzyu in November 2017. In a normal world, he would have been able to easily acquire RLD and test it against sample batches in June 2018. In a normal world, he would have filed his ANDA in January of 2019 with approval in September, and he would have launched within 30 days, that is to say, in October 2019.

This is consistent with Professor Hemphill's scenarios that assume Fera entry in the fourth quarter of 2019. As we have heard in the testimony, there is a strong evidentiary basis for Professor Hemphill's scenario that assumes Cerovene entry on or before October 2018 and Fera entry in October 2019.

I should note that, as Professor Hemphill testified, this is a very conservative model. First, it's conservative in that it does not model potential entry from two other firms that sought to enter the market, InvaTech and Mylan, because at the time we constructed the models there was not sufficient information to reasonably determine when these companies might have entered. It's always conservative in that we project

Cerovene entry in October 2018, although we now have testimony from Manish Shah at Cerovene saying that without the illegal conduct, Cerovene might have been able to enter as early as 2017.

Professor Hemphill considered just Cerovene and Fera and assumed Cerovene entry in October 2018 and Fera entry in October 2019 to calculate Vyera's Daraprim revenues, absent the illegal conduct.

The third step of Professor Hemphill's model is a simple mathematical calculation. In this step, he assesses the difference between Vyera's real-world revenues and the revenues that they would have made in the counterfactual world, where there was no illegality. By doing this, he determines the incremental revenue attributable to Vyera's conduct. Professor Hemphill calculates this access revenue, revenue but for the illegal conduct, to be $67.6 million.

Which brings us to the fourth and final step of Professor Hemphill's excess profits calculation. In the counterfactual world, where generics entered earlier, Vyera would have sold less Daraprim. Vyera's incremental costs, costs associated with the manufacturing of tablets and sales force costs, therefore, would have been lower in the but-for world.

So as a final adjustment, Professor Hemphill deducts the cost that Vyera would have avoided if Vyera were making and

selling less Daraprim. After deducting those costs, Professor Hemphill recently approximates that 64.6 million in excess profits were attributable to the illegal conduct.

Professor Hemphill's model incorporated assumptions that are well rooted in fact, so he has reasonably approximated the amount of unjust gain. Plaintiffs have met their burden under *Bronson*. As I mentioned, under *Bronson*, the burden then shifts to the defendants to show that our approximation of unjust gains is inaccurate.

Defendant's expert, Professor Jena, has done nothing to establish that Professor Hemphill's approximation is unreasonable. He raises no issue with Professor Hemphill's methodology. Instead, he notes generally, without any specifics, that Professor Hemphill has not provided a sound basis for determining the date of generic entry in the but-for world.

He also quibbles with Professor Hemphill's volume assumption, even though Professor Hemphill based those assumptions on the real-world data and on Vyera's own forecast. His thin and uncompelling criticisms do nothing but cast doubt on the accuracy of Professor Hemphill's analysis. Defendant's have, therefore, failed to meet their burden under *Bronson*.

Professor Hemphill has presented a reasonable approximation of ill-gotten gains, and we ask the Court to award at least $64.6 million of disgorgement to the plaintiffs.

As a last issue, should the Court award disgorgement in this case, Martin Shkreli should be held jointly and severally liable for the award. It is well established that the Court can exercise its discretion to impose joint and several liability in disgorgement cases. This discretion is properly exercised when defendants in a case have collaborated on the illegal scheme.

For example, in *SEC v. Pentagon Capital Management*, the Second Circuit found that joint and several liability was appropriate because defendants collaborated on a common scheme.

This principle also holds under state law. In *212 Investors Corporation v. Kaplan*, a New York state court observed that there is a significant body of authority holding that when apportioning liability for disgorgement, courts have the discretion to find joint and several liability when two or more individuals collaborate in the illegal conduct. Where joint and several liability applies in the disgorgement context, as it should here, there is no requirement to show that the ill-gotten profits personally accrued to the defendant.

As the Second Circuit noted in *SEC v. Contorinis*, where there is joint and several liability for disgorgement, the amount a court may order a wrongdoer to disgorge may not exceed the total amount of gain from the illegal action, but that does not entail that the gain must personally accrue to

the wrongdoer.

Whether an award of several and joint liability is appropriate is a fact-specific inquiry. The facts here clearly establish that the defendant should be held jointly and severally liable for the total amount of disgorgement.

Since Martin Shkreli hatched this monopolistic scheme, he has been a primary shareholder of Vyera's parent company and has significant voting rights. Any increased revenues that have benefited shareholders have benefited Mr. Shkreli first and foremost.

As we have heard from Ms. Haneberg, Mr. Shkreli also continuously exercised functional control over the company, even after he was in prison. Shkreli stayed in regular contact with Kevin Mulleady while Shkreli was in prison, collaborating with him regarding the operation and management of Vyera.

As your Honor knows, Shkreli's foliation of messages sent from Shkreli's illegal prison phone have prejudiced our ability to fully understand the scope of those discussions. But we do know, according to Kevin Mulleady's log, that Mulleady had over 1500 communications with Shkreli just in the seven-month period from December 2019 until July 2020, some of which pertained to the operation of Vyera.

And we know, from reported prison conversations, that Shkreli thought, as recently as 2020, that being on the board of Phoenixus means you're on the Martin and Kevin board. He

understood himself to be and in fact was controlling the company from prison. He was personally integrally involved in decision making at Vyera and was collaborating with Vyera executives to continue implementation of the illegal scheme that he had designed. If defendants have collaborated in an illegal scheme, imposition of joint and several liability is consistent with equitable principles. The Supreme Court recognized this in *SEC v. Liu* and remanded to the trial court there to determine whether the facts were such that Liu and his wife could be held jointly and severally liable. On remand, the trial court found that Liu's wife of was an active partner and accomplice in the scheme and imposed joint and several liability.

Here, Shkreli designed and maintained an illegal scheme that harmed not only competition but also consumers, the patients who are unable to obtain or afford Daraprim and those who were forced to pay its inflated price.

For his role in this scheme Martin Shkreli should be permanently banned from the pharmaceutical industry and should be held jointly and severally liable for a disgorgement award of at least $64.6 million.

Thank you, your Honor, for your time and consideration.

THE COURT: There has been a settlement publicly disclosed with respect to the codefendants in this action. So

how does that settlement agreement affect, if at all, the award that you seek here of disgorgement?

MS. McFARLANE: Sure, your Honor. Should your Honor find $64.6 million of disgorgement appropriate in this case and declare Mr. Shkreli jointly and severally liable, we do believe that equitable principles may require some setoff in the amount of what the settling defendants actually pay in the settlement.

THE COURT: Thank you.

MS. McFARLANE: Thank you, your Honor.

THE COURT: Mr. Casey, what is your preference? Would you like to take a brief recess before beginning?

MR. CASEY: Yes, your Honor, we would like to.

Your Honor, if I can mention one issue.

THE COURT: Sure.

MR. CASEY: It seems that our real time is not working. I noticed that plaintiffs appears to be. There may be something technical with this.

THE COURT: We will help you in the interim, but I am sure plaintiffs' counsel technical team will help you too.

The real, time the transcript.

MR. CASEY: It's coming up unintelligible.

THE COURT: While I am thrilled we have court reporters and we will rely on the transcript, I have actually not been looking at it during summations. I see my screen is working. One of my law clerks and court reporter will try to

assist you during that.

MR. CASEY: How much time, your Honor?

THE COURT: How much time do you want?

MR. CASEY: Fifteen minutes.

THE COURT: Sure.

(Recess)

MR. CASEY: Your Honor.

THE COURT: Mr. Casey.

MR. CASEY: Thank you, your Honor.

Before I begin, the defense has some timelines that we intend to use or allow the Court to look at during the presentation. I have copies here and these have been provided to plaintiffs' counsel this morning.

THE COURT: Thank you so much.

MR. CASEY: Your Honor, we will also have those available electronically when we get to those portions. They are just for the Court's assistance and the assistance of the plaintiffs.

Your Honor, on behalf of Martin Shkreli I want to thank the Court for your time and attention during this trial.

The first thing I wanted to do, your Honor, before I got into the substance of the argument, is to address just two points that came up during the plaintiffs' summation.

The first is, the Court asked about whether Mr. Shkreli's unhappiness with Mr. Tilles and the other

executives at Vyera that precipitated the proxy fight had to do with anything involving the anticompetitive scheme as alleged. Your Honor, the answer to that is no.

I would direct the Court to Mr. Shkreli's written direct testimony where he addresses this. It's at page 12. This is DX-546 at page 12 where he addresses the proxy fight. I believe the first part was presented by the plaintiffs, paragraph 61.

What was not presented was the next paragraph, 62. That says: The proxy fight was totally unrelated to Vyera's sale and distribution of Daraprim. Then paragraph 63 says: Despite the fact that my share ownership in Vyera allowed me to make changes to the board of Phoenixus, I never used that power to affect in any way Vyera's distribution of Daraprim, its acquisition of pyrimethamine API for Daraprim, or its policies and practices related to reporting of data.

That's unrebutted testimony from Mr. Shkreli. It clearly shows that there is not a connection between his exercising his authority or his ownership, his rights as a shareholder, and the company's sale of Daraprim. There is no record evidence to suggest that he was directing Vyera's conduct relating to Daraprim or the distribution of Daraprim during the period after he left the company. That's the first item I wanted to discuss.

Secondly, your Honor --

THE COURT: When you say that, no evidence that he directed Vyera's conduct relating to Daraprim or the distribution of Daraprim after he left the company, what date are you using for after he left the company?

MR. CASEY: He left as CEO in December of 2015, your Honor.

THE COURT: Yes. But for that last statement is that the date you are using?

MR. CASEY: Well, for that I would use the date that he actually left the board, which was February 2016.

THE COURT: Your contention is following February of 2016, he did nothing to affect the company policy with respect to Daraprim?

MR. CASEY: Yes, your Honor. I think what I would say is, there is record evidence that he made suggestions as a shareholder about the direction of the company and those suggestions included in some cases Daraprim. But there were merely suggestions and there is also record evidence that the executives did not -- in many cases did not act on those suggestions, so he wasn't directing the policy. In other words, he may have made suggestions, but it wasn't -- there is no record evidence that I'm aware of that he actually directed the distribution of Daraprim and that the executives furthered -- carried out those directives.

THE COURT: That's a little tough, I think,

proposition, given this record and given the transcripts of his calls for the period after February of 2016.

MR. CASEY: Your Honor, there are transcripts of phone calls for certain, and we don't dispute that. What I'm saying is, those transcripts reflect discussions he had with the executives, including Mr. Mulleady, suggestions about company business. But in most cases those suggestions were not acted upon. So he was not controlling company decisions during that period of time. There is evidence from the executives, including Ms. Costopoulos, Mr. Salinas, others that confirmed that, that he wasn't controlling the company while he was out of the company.

THE COURT: Let's take one example during the period you're focusing on, the period after February 2016, of the discussions about RL Fine. If you're planning to address those later --

MR. CASEY: I was not, your Honor.

THE COURT: What about his suggestions or directions with respect to how to engage with RL Fine after they learned that generics were looking to RL Fine for supply of the API?

MR. CASEY: Your Honor, what I'm aware of is one e-mail in the record in which Mr. Shkreli suggested what the company should order from RL Fine. That e-mail did not direct them to form an exclusive contract with RL Fine and there is testimony from Mr. Mulleady that the reason that he was -- I

think there was a follow-on e-mail saying I'll keep you in the loop on these communications going forward. Mr. Mulleady testified just the other day that he was relying on Mr. Shkreli's expertise in the pharmaceutical industry in terms of what should be in that e-mail. But there is no record evidence of a direction from Mr. Shkreli to the company to form an exclusive deal with RL Fine. It just doesn't exist.

THE COURT: Thank you, counsel.

MR. CASEY: Thank you, your Honor.

One other thing I wanted to address, your Honor. The plaintiffs said that Mr. Shkreli is blaming others, blaming the generic companies, blaming the FDA.

Your Honor, that's not what is happening here. Mr. Shkreli is not blaming anybody. In fact, he has taken responsibility in his affidavit for some conduct, including the price increase, which he takes responsibility for, and for some of the fallout after that.

But what our argument is is simply holding the plaintiffs to their burden of proof. They have a burden to establish causation. They have a burden to establish that there was a substantial anticompetitive effect in the market. Our argument is they have not met that burden.

That's what I plan to go into with the Court today, is to discuss some of those pieces of record evidence that suggest, we think strongly -- I wouldn't say suggest -- that

show that plaintiffs haven't met their burden.

It's not debatable that under the rule of reason plaintiffs bear the initial burden -- and I'm quoting from *Ohio v. American Express*, Supreme Court decision, 2018 -- the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market.

That's plaintiffs' burden. They have to show that these restrictions and this scheme, as they put it, actually delayed the generics in entering the market. The record evidence does not show that, your Honor.

The reason it doesn't is because there were lots of things going on. There were filings at the FDA. There were business decisions that these generic companies were making. There is also a lack of evidence of a connection between the agreements and the refusals to deal that are alleged in the complaint. That's what I would like to go through this morning, this afternoon.

THE COURT: You are conceding that the goal, Mr. Shkreli's goal, was to impede generic entry through the measures he took or directed, but you are arguing that, despite that goal, he failed to achieve his purpose.

MR. CASEY: Your Honor, on that I would say there is record evidence from which the Court could conclude that there was an intent to impede generics. That was not only

Mr. Shkreli, but it was other executives at the company. We have heard testimony that it was -- that topic, that discussion was held at the company. But, as the Court knows, anticompetitive intent is not sufficient. They have to prove that there was an actual substantial anticompetitive effect. They have not shown that.

As I said, the record shows that each of the generic companies made multiple business decisions and FDA filings that impacted the timing of approval of their ANDAs.

The record does not support a finding that the challenged agreements caused actual delay in the generic's ANDA approvals. As this Court said in the *Lavoho LLC v. Apple, Inc.* case, this is 232 F.Supp. 3d 513 (S.D.N.Y. 2016), at page 525 this Court said: "Lack of causation in fact is fatal to the merits of any antitrust claim."

Further, the plaintiffs have failed to meet their burden to prove a relevant product market of FDA-approved pyrimethamine products.

Finally, even if the Court determines that plaintiffs have met their burden, the relief that they seek is not warranted. There are now three companies selling generic Daraprim, so there was no need for an injunction to preserve competition in the market.

Plaintiffs' requests for a pharmaceutical industry ban amounts to a penalty provision that is inappropriate for a

court of equity. Plaintiffs' request for equitable monetary relief against Mr. Shkreli which relies upon a joint and several liability theory is legally and factually unsupported.

Now, with that introduction, your Honor, I would like to just go through, if I may, starting with Cerovene, the timeline that you have, the first timeline is Cerovene that deals with their API sourcing.

So the first broad point, your Honor, is Cerovene was able to source API. That's clearly in the record. Starting in 2013 and 2014, Cerovene obtained API from Ipca to support its ANDA. Cerovene filed its ANDA on May 8, 2014. That's not in the timeline, your Honor. The portions that are I will get to.

In January 2015, the FDA issued an import alert preventing importation of Ipca's API into the U.S. Forced to find a new source of API, Cerovene looked to just two companies, Fukuzyu and RL Fine, to get API. Cerovene made no effort to identify API suppliers other than those two. Mr. Shah testified to that.

With respect to Fukuzyu, in 2015, Cerovene began negotiating with Fukuzyu for API suppliers to supply.

(Continued on next page)

MR. CASEY: (Continuing) In September of 2015, Fukuzyu provided Cerovene with a small amount of pyrimethamine API for testing. And then in October 2015, Cerovene wrote to the FDA — and this is, again, a common theme here, as if there's many, many FDA filings — Cerovene wrote to the FDA seeking an exemption from the Ipca import ban.

Now, we fast forward to March of 2016. Cerovene and Ipca jointly asked the FDA for an exemption. And in July 2016, Cerovene contacted Fukuzyu again, after the FDA had denied the exemption.

On September 9 of 2016, Cerovene told its broker that it wished to place an order with Fukuzyu for 50 kilograms of pyrimethamine API.

And then in October 4th -- on October 4th of 2016 — and this is in your timeline, your Honor, in green there — Fukuzyu told Cerovene that it would not supply the API, citing low demand for pyrimethamine and high risk with the business.

Now, this denial by Fukuzyu occurred several months before the Fukuzyu-Vyera master services agreement, which, as the Court knows, happened on January 25th of 2017, and there is no evidence that the later-in-time agreement between Fukuzyu and Vyera had any effect on Fukuzyu's refusal to sell API to Cerovene.

Let's talk about RL Fine.

In 2016, Manish Shah of Cerovene learned of RL Fine as

a potential API supplier. On November 16th of 2016 — again, this is on your timeline, your Honor, in green — Cerovene and RL Fine entered into an exclusive supply agreement for four years.

Now, Cerovene believed that exclusivity was important to ensuring a viable commercial supply of API. We heard that from Mr. Shah at trial.

Cerovene purchased enough API from RL Fine under the November 16, 2016 agreement for its bioequivalency testing for the launch of its generic Daraprim product.

On November 30 of 2017, RL Fine stopped supplying pyrimethamine API to Cerovene. And, again, in terms of the timing, this agreement was more than a year before the RL Fine agreement with Vyera, which was December 27th of 2017. There is no evidence that the later-in-time agreement between Vyera and RL Fine had any effect on RL Fine's decision to stop supplying API to Cerovene.

In April of 2020, RL Fine delivered more API under that November 16, 2016 agreement. And on February 19, 2019, Cerovene executed a supply agreement for a company we're referring to as API-3 to supply pyrimethamine API if Cerovene received FDA approval to use API-3 as its API supplier.

THE COURT: I just want to backtrack a moment to make sure I've captured your point.

MR. CASEY: Okay.

THE COURT: Your point with respect to Cerovene and API supply is, one, they only identified Fukuzyu and RL Fine as realistic suppliers of API?

MR. CASEY: I don't know if I would say that, your Honor. I think the record evidence is that they're the only two that they reached out to.

THE COURT: Okay. The only two that they reached out to. And your argument, with respect to that, is that they should have reached out to more than those two?

MR. CASEY: Well, there are lots of other companies, and there were at that time, yes.

THE COURT: Who else, in the record, was a manufacturer of pyrimethamine?

MR. CASEY: At that time?

THE COURT: Yes.

MR. CASEY: I don't have that available at this point, your Honor, but there were others.

THE COURT: Okay.

And then with respect to Fukuzyu, just to make sure I understand your point, you think there is no record evidence that Fukuzyu declining to supply Cerovene with API, that there's no record evidence that that refusal by Fukuzyu can be linked to Vyera's conduct?

MR. CASEY: There's no record evidence that that refusal can be linked to the challenged agreement in the

complaint, which is the January 25th, 2017 agreement.

THE COURT: So you're not saying there's no evidence that it can be linked to Vyera's efforts to negotiate that agreement; your argument is sort of a legal one, that any activity by Vyera before the agreement was actually executed is irrelevant?

MR. CASEY: I don't know if I would say that, your Honor, but this came up in the examination of the plaintiffs' expert, Mr. Bruno. Mr. Bruno testified -- and he was asked about this, and whether the negotiations could have affected -- if negotiations were going on at the time of the refusal, whether they could have affected the refusal. I mean negotiations between Vyera and Fukuzyu.

And he said that he didn't see any evidence that Vyera insisted that Fukuzyu decline to supply Cerovene on October 4, 2016. He was asked the same thing with respect to the RL Fine refusal, and he said the same thing, he said he did not see any evidence that Vyera's agreement with RL Fine on December 27, 2017, prevented RL Fine from supplying Cerovene with API in November 2017.

THE COURT: Okay. I think with respect to RL Fine, I heard you say a moment ago — and I may have misheard — that RL Fine's refusal was a year before RL Fine signed the agreement with Vyera. But you're saying it was a month before?

MR. CASEY: If I did say that, I misspoke, your Honor.

THE COURT: Okay, good. Thanks. I just want to make sure I capture your argument.

MR. CASEY: Okay.

Now, if we can move on, then, your Honor, to the next timeline, which is I'm going to focus on Cerovene's accessing RLD. That's the timeline that's where the boxes are orange.

Again, first, the main point is that Cerovene was able to obtain RLD for bioequivalence testing. On April 3rd, 2017 — and this is going before the timeline that you have in front of you — Cerovene filed a major amendment to its ANDA to notify the FDA that it was substituting RL Fine for Ipca as its API supplier.

On December 26th of 2017, the FDA issued a complete response letter to Cerovene which directed Cerovene to conduct new bioequivalence testing using the new API supplier, RL Fine.

And even though there was some risk that the FDA would require new bioequivalence testing, during the period April 3rd and December 26, 2017, Cerovene made no attempt to obtain new RLD; instead, it simply waited for the FDA to respond to its major amendment.

On January 22nd, 2018, Cerovene asked the FDA to reconsider its decision requiring new bioequivalence testing. Cerovene did not want to commit the $600,000 it would have to spend acquiring RLD until the FDA acted on its request. We heard that from Mr. Shah at trial.

On March 12 of 2018, Cerovene sent FDA a follow-up letter demanding an answer to its request for reconsideration. And on April 6, 2018, the FDA denied the request for reconsideration.

Now let's talk about the RLD purchase orders that Cerovene made.

On December 30, 2017, Cerovene placed a purchase order with a procurement company called Espee.

On February 20, 2018, Cerovene canceled the Espee order. And in February 2018, Dr. Reddy's, Cerovene's marketing partner, identified ProSupplier as a possible procurement partner and urged Cerovene to partner with ProSupplier. Cerovene, instead, went with Reliant, and in February 2018, placed an order for five 100-count bottles with Reliant.

Cerovene's decision to go with Reliant as opposed to ProSupplier was based on assurances that Cerovene received from Reliant, that Reliant could obtain the samples quickly, and that didn't happen. Reliant did not make good on these assurances and repeatedly asked Cerovene for additional time.

Cerovene had no reason to believe that ProSupplier could not have supplied Daraprim RLD to Cerovene in February 2018 if Cerovene had placed an order with ProSupplier at that time. Again, Mr. Shah testified to that.

In June of 2018, Reliant delivered one of the five bottles that Cerovene had ordered.

And then on July 13, 2018, Cerovene wrote to the FDA asking for a waiver from the five-bottle requirement.

Following that request, Cerovene continued to wait for Reliant to deliver the additional four bottles rather than switch to ProSupplier, as its more established pharmaceutical partner, Dr. Reddy's, was urging Cerovene to do. Dr. Reddy's believed that ProSupplier could deliver the requested bottles within two to three weeks.

And in September 2018, Cerovene finally relented and agreed to place a purchase order with ProSupplier for three 100-count bottles rather than five.

Justin, if we could get up, please, DX 168.

Your Honor, I just wanted to show you a document that's been admitted and was used in the Cerovene examination. This is an email which shows Dr. Reddy's business plan to put two orders out to both Reliant and ProSupplier, but not to order five bottles, but to, rather, order a maximum of three. I'm not going to read the whole thing, but the Court's familiar with it from the trial testimony.

It's clear, from this email and from the other testimony, that Cerovene and Dr. Reddy's were making a business decision to limit the number of bottles they were going to order at a time when they still had the FDA requirement of five bottles, and, instead, they ordered three to control the risk, and so that if one supplier was able to deliver just a couple

of bottles, they would get a refund from the other. Again, this is the kinds of business decisions that were being made by the generic companies.

Now, the order with ProSupplier, which was in September, was placed after Cerovene had sought the FDA waiver, as I mentioned, but before it was granted. The waiver was not granted until April of 2019. So they knew they were required to get five bottles, but they got three, and asked for a waiver from the FDA in the meantime. And they took the risk that the FDA would deny the waiver request, but they didn't want to spend the extra money to obtain the five bottles.

Dr. Mukhopadhyay, of Dr. Reddy's, testified that if Dr. Reddy's had known that the FDA had not granted the request for the waiver, Dr. Reddy's would have advised Cerovene to order five bottles instead of three.

And then on October 17 of 2018, Cerovene made its initial payment to ProSupplier for the RLD, and about a month later, November 19, 2018, ProSupplier obtained three bottles, and ProSupplier was, of course, the company that Cerovene chose not to go with back in February.

And Dr. Mukhopadhyay, of Dr. Reddy's, testified that there's no reason Cerovene could not have ordered the required five bottles from ProSupplier — five bottles rather than three — and no reason it could not have obtained five bottles instead of three.

Now, following the order with ProSupplier and the obtaining of the RLD, Cerovene waited. They waited until the FDA approved its use of the three bottles, and, again, that happened on April 19, 2019, to conduct the bioequivalence testing. And in May and June of 2019, following the waiver grant — the grant of the waiver — Cerovene conducted the bioequivalence testing using the three bottles that ProSupplier had obtained.

Moving forward, September 4 of 2019, Cerovene reported the results of its bioequivalence testing to the FDA.

February 28, 2020, the FDA approved Cerovene's ANDA.

And then less than a month later, March 19 of 2020, Cerovene and Dr. Reddy's jointly announced the commercial launch of the generic Daraprim product.

So, in summary, your Honor, in terms of the timeline for the RLD purchases, any delay in receiving the required amount for the bioequivalence testing is attributable to the following factors:

First, Cerovene's decision to not look for RLD during the period April 2017 to December 2017, while the FDA considered Cerovene's major amendment, stating that it was switching to RL Fine as its API supplier.

Two, the Ipca import ban, which required Cerovene to start from scratch, beginning on December 26, 2017, to find new RLD.

Third, Cerovene's decision not to follow the recommendation of its more established partner, Dr. Reddy's, and, instead, to choose Reliant over ProSupplier to obtain RLD as Reliant could not live up to its representations that it could access the RLD quickly.

Fourth, Cerovene's decision that upon receiving only one bottle from Reliant in June 2018, to ask the FDA for a waiver of the five-bottle requirement and purchase three bottles rather than five, once it finally agreed to use ProSupplier in September 2018.

And then, fifth, Cerovene's decision to not immediately conduct bioequivalence testing once it received the three bottles from ProSupplier on November 29, 2018, but, rather, to wait for FDA approval of its request on April 19, 2019.

I was going to move on to Fera now, your Honor.

So there is a Fera timeline, your Honor. On that timeline, there is both the API portion, the boxes that are in green, and the blue boxes are the RLD portions of the discussion.

First, just focusing on API, the global point, again, is that Fera was able to access API.

With respect to Fukuzyu: Fera made two attempts to contact Fukuzyu to inquire about its ability to supply pyrimethamine API. In late 2015/early 2016, the first attempt

was an email from Genevieve Della Fera, and there was no response from Fukuzyu. There is no record evidence that Fera followed up.

The second outreach took place after Fera made the business decision to form a contract with another API supplier, referring to that supplier as API-1, and around eight months after Fukuzyu entered the exclusive contract with Vyera in January 2017. At no point prior to this second outreach did Fera make another attempt to reach out to Fukuzyu.

With respect to API-1, in March of 2016, Fera approached two possible API suppliers, including API-1, at DCAT, the conference that you heard testimony about. API-1 did not at the time, and does not now, have a DMF. Fera did no due diligence on API-1 other than confirming it was a reputable company.

On June 13, 2016, API-1 and Fera entered a confidentiality and exclusivity agreement. Fera selected API-1 approximately seven months before Vyera entered into the MSA with Fukuzyu and approximately 18 months before Vyera's agreement with RL Fine. Therefore, Vyera's supply agreements with Fukuzyu and RL Fine could not have affected Fera's decision to go with API-1.

Now, API-1 estimated 34 to 40 weeks to develop pyrimethamine. Ultimately, API-1 completed its first batch of pyrimethamine in October of 2017. Fera is unaware of the

reasons why it took API-1 approximately six months longer than its estimate.

On April 6, 2018, Fera and API entered into a second agreement, a ten-year mutually exclusive supply agreement, for pyrimethamine.

So now I'm moving to the discussion of RLD.

Fera was able to access RLD.

In June of 2017, Fera received a purchase agreement from Vyera for the sale of 13 30-count bottles of Daraprim from Vyera.

The purchase agreement permitted Fera to use the Daraprim tablets to conduct bioequivalence testing. Rather than sign the agreement and obtain the Daraprim RLD directly from Vyera, Fera, without consulting an attorney, struck out the entirety of an indemnity clause and returned the edited document to Vyera. Negotiations ended after the wholesale deletion of this provision.

In October 2017, Fera got small quantities for initial testing by having a doctor write two prescriptions, which a local pharmacy filled within a couple of days.

Now, moving on to negotiations with a company called Tanner: In December 2016, Fera received an offer from Tanner Pharma to sell Fera 100-count bottles of Daraprim. At that time, Fera had no reason to believe that Tanner could not have supplied it with Daraprim, but Fera did not place a purchase

order.

In January 2017, Tanner offered to sell Fera up to seven 100-count bottles of Daraprim. Again, Fera did not make a purchase order.

Moving forward to September of 2017, Tanner made a third offer to supply Daraprim to Fera, and, again, no offer.

Throughout its dealings with Tanner, Fera was concerned over price. To address this, Tanner sent Fera a signed escrow agreement that Fera had edited and emailed to Tanner for execution. Fera never countersigned the agreement and never placed an order.

And so, to sum up, Fera had three opportunities to place a purchase order for RLD with Tanner but never placed an order.

Now, moving to another topic with respect to Fera's access to RLD: On October 25, 2017, Fera sought a pre-ANDA meeting with the FDA to conduct a pharmacokinetic study for its bioequivalence testing, which would not require Fera to use any RLD.

On December the 1st, 2017, the FDA denied Fera's request without a meeting.

Now, moving on to Fera's purchases from Reliant:

Having had its request denied, Fera finally determined to place an order for RLD and did so through Reliant.

On January 22nd, 2018, Fera placed an order for two

bottles with Reliant. Fera received the two bottles eight days later.

Fera knew about the FDA's five-bottle requirement and had the opportunity to purchase five bottles in January 2018, and could have through Reliant but it opted not to.

On February 12, 2018, Reliant offered to procure more bottles but Fera declined, saying, "we are good for now." Fera opted not to purchase additional bottles because it made the decision to quote-unquote derisk the purchase. We heard that from Ms. McDougal.

Fera opted to seek a waiver of the FDA's five-bottle requirement even though it later acknowledged that, quote, the FDA's general policy is not to waive the five-times testing requirement.

On August 24, 2018, seven months after buying two bottles of RLD from Reliant, Fera sent FDA a letter seeking a waiver of the five-bottle requirement. The FDA denied this request in January 2019.

Three months later, Fera tried again, in April 2019, sending a letter to the FDA, but not disclosing to the FDA that it had opportunities to buy five bottles but declined.

On June 4, 2019, the FDA granted the waiver.

Now, there was another series of events happening with Fera around this time relating to its CMO, contract manufacturing organization. Fera encountered delays with its

CMOs that had nothing to do with Vyera's distribution agreements. Fera terminated its first CMO with Xcelience in July of 2017 and hired a new CMO, Latitude, in November of 2017. Latitude completed developing the prototype for generic Daraprim in August 2018, and Fera then hired a company called Rivopharm as its CMO to manufacture Daraprim tablets for use in stability and bioequivalence studies.

The tech transfer from Latitude to Rivopharm was not implemented until October of 2018, and Rivopharm did not manufacture the first batches of Daraprim until March 2019.

So, prior to March 2019, Fera could not have done stability and bioequivalence testing because its product wasn't finished.

And then Fera submitted its ANDA on December 19, 2019, and got approval on June 27, 2021.

So, in summary, any delay in Fera submitting its ANDA was caused by its own business decisions and FDA filings, including the following:

Fera's business decision to proceed with API-1 after Fukuzyu did not respond to Fera's initial outreach, and API-1's failure to meet its projected timeline for production of API.

Two, Fera's business decision to buy only two bottles of RLD instead of five.

Three, Fera's waiting seven months, from January to August 2018, after buying the two bottles, to seek an FDA

waiver.

Fourth, Fera's strategic decision to pursue a time-consuming and uncertain waiver from the FDA.

Five, Fera's waiting three months, from January to April 2019, to submit a second request to the FDA after the first one was denied.

And then, finally, Fera's business decision to switch CMOs.

So that's the Fera discussion, your Honor.

Now, moving to InvaTech — and that's the last of the timelines, your Honor — again, InvaTech obtained RLD. And I'll do these in reverse order now, your Honor, for InvaTech because the RLD discussions are pretty brief.

InvaTech decided on Daraprim generic in 2014.

In October 2014, InvaTech bought six 100-count bottles from a pharmacy in New Jersey.

InvaTech completed its bioequivalence testing in 2016, using those samples and pyrimethamine API from RL Fine.

InvaTech has had no need for additional samples of Daraprim to conduct bioequivalence testing since it completed that testing in 2016.

Now, moving on to API:

InvaTech obtained API. Like Cerovene, InvaTech originally was supplied by Ipca, but after the import ban, it was forced to find a new API supplier.

On February 17, 2017, InvaTech and RL Fine entered a preliminary collaboration agreement whereby RL Fine would supply InvaTech with three APIs, including pyrimethamine. This collaboration agreement was ten months before the Vyera-RL Fine agreement.

The collaboration agreement required RL Fine to submit a DMF for pyrimethamine but RL Fine did not do so.

By January 2017, InvaTech was ready to file its ANDA, but RL Fine had not yet submitted its DMF.

Therefore, in July 2017, InvaTech submitted DMF materials for RL Fine in the CMC-section of the ANDA.

InvaTech filed its generic Daraprim ANDA on July 28, 2017.

Now I will discuss RL Fine's decision to stop supplying API to InvaTech. In December of 2017, InvaTech contacted RL Fine for help responding to the FDA's questions regarding its generic Daraprim ANDA. RL Fine informed InvaTech by phone that it would no longer support InvaTech's ANDA. Mr. Patel of InvaTech flew to India and was told that Daraprim was too small a product for RL Fine to continue supporting InvaTech's ANDA.

RL Fine's decision to not support InvaTech's ANDA came approximately ten months after the Cerovene-RL Fine agreement, which, by its terms, prevented RL Fine from supplying pyrimethamine API to InvaTech. More importantly, it came

approximately three months before Vyera's agreement with RL Fine. There is no evidence that the later-in-time agreement between Vyera and RL Fine had any effect on RL Fine's decision to stop supplying API to InvaTech.

Thus, Vyera's agreement with RL Fine could not have affected RL Fine's decision to not support InvaTech's ANDA.

Now, InvaTech -- we'll discuss and InvaTech and API No. 2. There's an API manufacturer we're referring to as API-2. InvaTech then needed a new source of API, and it found one in API-2. API-2 did not have a DMF on file, and it never manufactured pyrimethamine API before. API-2 was the only company that InvaTech looked at, considered, as an API supplier after it stopped working with RL Fine, and InvaTech did not do any due diligence on API-2.

It took API-2 approximately six months to develop a process for developing pyrimethamine API.

Now I'm going to discuss FDA responses to InvaTech.

Going to the next timeline, the next page:

On May 22nd, 2018, InvaTech received a complete response letter from FDA identifying over 50 deficiencies regarding InvaTech's ANDA.

InvaTech worked with API-2 to gather information to respond to the FDA, and did so 14 months later, on July 31st, 2019.

On January 24, 2020, the FDA sent another letter

identifying an additional 20 issues to be addressed by InvaTech. InvaTech experienced delays relating to COVID-19, and only recently responded to the complete response letter in the fourth quarter of 2021.

So, in sum, with respect to InvaTech, any delay in InvaTech's pursuit of its ANDA was caused by the following, none of which is attributable to Vyera:

One, the Ipca import ban, which required InvaTech to find a new source of pyrimethamine API.

Two, RL Fine's delays in filing a DMF for pyrimethamine between 2015 and 2017.

Three, RL Fine's decision to stop supporting InvaTech's ANDA in September 2017 before the RL Fine supply agreement but after the RL Fine-Cerovene exclusive agreement.

And then, finally, recent delays caused by COVID-19.

Now, your Honor, I know that was a lot, and I appreciate you listening through that, but I'm done with that section.

Excuse me one second.

(Pause)

MR. CASEY: Your Honor, at this point, I'd like to talk about the data-blocking agreements.

The data-blocking agreements had no effect on the market. These agreements were entered after all the generic companies in this case had already assessed the generic

Daraprim market opportunity. There were two data-blocking agreements.

First was an ASD agreement — Vyera and ASD agreed — and that agreement was dated September 12 of 2017. And then Cardinal Health and Vyera reached a data-blocking agreement, and that was dated September 20, 2017.

So Cerovene, Fera and InvaTech also assessed the market opportunity prior to those agreements. Cerovene assessed the market for Daraprim in 2013, four years before the data-blocking agreements were entered. Cerovene decided to enter and relied upon publicly available data rather than IQVIA data to make its assessment.

Fera had a thorough opportunity to assess the market for generic Daraprim in late 2015 and early 2016. Public data and IQVIA data from 2014 showed the market opportunity at 1 million tablets, so Fera clearly overestimated the market opportunity.

InvaTech assessed the market opportunity for Daraprim in 2014 based on publicly available IQVIA sales data.

The plaintiffs' economic expert, Professor Hemphill, provided no opinion on the data-blocking theory, and so in conclusion, the plaintiffs' data-blocking theory has absolutely no support in the record.

I'd like to talk about Vyera's distribution system now, your Honor. The Vyera distribution system expanded access

to Daraprim, and there's lots of record evidence of this.

Vyera inherited the specialty distribution system from Amedra and Impax, the previous owners of the rights to Daraprim. Amedra's specialty distribution agreements only licensed two specialty distribution pharmacies to distribute Daraprim — Walgreens, which had the exclusive right to distribute Daraprim directly to patients, and ICS, that had the exclusive right to distribute to hospitals and government entities. Vyera added four additional specialty distributors — ASD Healthcare, Biorich Pharma, Cardinal Specialty, and Optime.

Vyera amended its distribution agreement with Walgreens that it inherited from Amedra to remove its exclusivity provisions.

Vyera then significantly increased the number of specialty pharmacies that could sell Daraprim to patients.

Vyera, likewise, added significant patient support services to the Daraprim distribution system through contracts with Asembia LLC and Optime.

Vyera instituted a hub as a, quote, key intake for the patient, quote, to ensure that patients were able to access the benefits, the copay benefits and the affordability benefits, that Vyera was offering. That's from the trial testimony at Christina Ghorban.

And Vyera expanded the distribution to state ADAP programs, the AIDS Drug Assistance Programs. And, again,

that's from the testimony of Christina Ghorban.

In terms of supply agreements: Exclusive supply agreements are common in the industry. As the Second Circuit has said, exclusive supply agreements often, "have pro-competitive purposes and effects, such as ensuring steady supply for the protection against price fluctuations, reducing selling expenses, and promoting stable long-term business relationships." The case is *Geneva Pharm. Tech. Corp.*, 386 F.3d 485 at page 508 (2d Cir. 2004).

THE COURT: Which of those do you think was most relevant to the analysis of the Fukuzyu and RL Fine supply agreements?

MR. CASEY: Which of what, your Honor?

THE COURT: Those pro-competitive effects.

MR. CASEY: Well, I think, certainly, it assured a steady supply. We had testimony on that from, I believe it was Dr. Salinas.

THE COURT: Of the actual agreements, I'm talking about, not generally, but in this case --

MR. CASEY: Right.

THE COURT: -- of the agreements at issue, what are the pro-competitive effects?

MR. CASEY: I think that the agreements -- well, the Fukuzyu agreement assured a steady supply. Afforded protection against price fluctuations, I'm not sure about that, I don't

know if there's record of evidence of that, but, certainly, I think it promoted a stable relationship with Fukuzyu.

THE COURT: Thank you.

MR. CASEY: And so exclusive supply agreements are, thus, presumptively legal. That's from the case *CDC Techs, Inc. v. IDEXX Labs, Inc.*, 186 F.3d 74, at page 80 (2d Cir. 1999).

We had several witnesses testify to the benefits of the exclusive supply agreements in this case. Manish Shah, the president of Cerovene — and this gets, I guess, to your question, your Honor — Manish Shah testified that Cerovene wanted an exclusive supply agreement with RL Fine so that Cerovene could ensure that RL Fine is able to supply Cerovene with a commercial quantities of the API that Cerovene needed. Dr. Salinas testified that exclusive supply agreements are very common, and, according to John S. Russell, the defense expert, exclusive API agreements are common in the pharmaceutical industry and are used to maintain high quality, avoid drug shortages and protect revenues. That's the John Russell written direct at paragraph 104.

Now, your Honor, I wanted to get back to something that you mentioned in the plaintiffs' presentation, that came up during the trial, and that is the issue of whether Vyera's API was set to expire. You asked if there was record evidence of that. There is, your Honor.

I'd like to show you DX 511. This is a document that Mr. Russell cited in his written direct testimony. If you'll see that first bullet point, this is a Turing meeting notes.

There it is. It says, the second bullet there, current API inventory of, roughly, 76 kilograms to expire in August 2016. So this memo is, as you go up to the top, the date of the memo, so as of January 12, your Honor, the projection was that the API inventory would have expired in August of 2016.

THE COURT: So the inventory acquired in 2015, the entirety of the inventory, was to expire in August of 2016?

MR. CASEY: Yes.

THE COURT: And so when did Vyera need additional inventory, then, from Fukuzyu?

MR. CASEY: Well, your Honor, I know that, of course, the agreement was about a year later, January of 2017, but I believe there's record evidence that there were discussions prior to that time about the need to get a supply agreement during that period of time.

THE COURT: Yes. But when did it next order pyrimethamine from Fukuzyu because its entire inventory of API expired in August of 2016?

MR. CASEY: I don't know the answer to that, your Honor. I could get you that evidence, but I'm not aware of it at this point.

THE COURT: Thank you.

MR. CASEY: It does say that its projection is, it will expire, not that it has expired. Its projection in January was that it would expire in August.

THE COURT: Thank you.

MR. CASEY: Certainly.

And then, finally, on exclusive supply agreements: Both Cerovene and Fera entered into exclusive supply agreements, as the Court is aware, with RL Fine and API-1 respectively.

Now, I'd like to move on now to the product market discussion. Of course, the threshold element plaintiffs must establish, under either Section 1 or Section 2 of the Sherman Act, is harm to competition in the relevant market.

And in the case *U.S. Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, at page 64 (2d Cir. 2019), the Second Circuit said, "The relevant market must be a market for particular products or services, the outer boundaries of which are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." And that passage quoted the Brown Shoe case, *Brown Shoe Company v. United States*.

So now, neither the reasonable interchangeability of use nor the cross-elasticity of demand support plaintiffs' proposed relevant product market of FDA-approved pyrimethamine.

So just focusing on interchangeability: That standard looks to the use or function of the given product as compared to other products. That case is *Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F.Supp.2d 569, 575 (S.D.N.Y. 2011).

Now, the evidence in this case is uncontroverted that TMP-SMX, atovaquone, and compounded pyrimethamine are medical alternatives for treating patients with active toxoplasmosis and for prophylaxis.

(Continued on next page)

MR. CASEY: Dr. Hardy testified to that, the plaintiffs' expert.

The evidence showing decision making of actual physicians supports the conclusion that all of these alternative therapies are within the proper standard of care, as explained by plaintiffs' own expert, Dr. Hardy. The fact that FDA approved pyrimethamine is the gold standard for active toxoplasmosis and that TMP-SMX is the gold standard for toxoplasmosis prophylaxis only shows that these alternative treatments are better options for certain patients, not that they are each their own relevant product market.

Now, turning from the interchangeability to the cross elasticity of demand, the cross elasticity is related to interchangeability. It requires a consideration of the extent to which a change in the price of one product will alter the demand for another product.

Professor Hemphill admitted that he did not have quantity and price data for TMP-SMX, atovaquone, or compounded pyrimethamine to use cross elasticity of demand to establish a relevant product market.

In summary, in terms of the relevant product market, which is plaintiffs' burden, the real-world evidence of substitution, the choices that consumers are actually making when treating toxoplasmosis establishes that there are several alternative therapies for toxoplasmosis, depending on the

patient, the type of toxoplasmosis, and the price of the alternative treatments. Plaintiffs have failed to prove -- to meet their burden of proof that FDA-approved pyrimethamine is a proper relevant product market.

Your Honor, I want to move -- I am nearing the end of my presentation, your Honor. I wanted to talk a little bit about Mr. Shkreli's -- the plaintiffs' claim that he should be held individually liable. Again, this gets back to a discussion we had earlier.

We heard a lot of evidence of Mr. Shkreli exercising influence as a large shareholder of Phoenixus. But there has been no evidence presented of his direction of or participation in the challenged agreements. There is no evidence to show that he negotiated or signed --

THE COURT: Let me make sure I have that formulation. No evidence of his direction or what?

MR. CASEY: Participation in the challenged agreements.

THE COURT: Thank you.

MR. CASEY: You're welcome.

There has been no evidence that he negotiated or signed the Fukuzyu or RL Fine agreements which were entered after he left the company, nor has there been any evidence to show that he negotiated or signed any of the challenged distribution agreements, nor that he is familiar with any of

the terms of those agreements.

At this point, your Honor, I would like to move on to the relief issues, injunctive relief and equitable monetary relief. Plaintiffs have asked for an industry ban. This morning it appeared that they were asking for a lifetime ban. It's not clear to me whether that's in fact what they are seeking. In their pretrial memo they asked for at least a 20-year ban. But, in any event, they are asking for a significant industry ban from the Court.

Here, your Honor, this obviously is an issue for your discretion. This is an equity court. In our view, any injunctive relief, if the Court disagreed with us and believed that Mr. Shkreli should be held liable, the question is, what is the consequence of that? Any injunctive relief should be narrowly tailored to the specific violations and avoid unnecessary burden on lawful commercial activity. That's a quote from a case called *Syntel Sterling Best Shores Mauritius Ltd. v. Trizetto Group, Inc.*, 2021 WL 1553926 at page 14 (S.D.N.Y. April 20, 2021)

Your Honor, the plaintiffs concede in their pretrial brief that an industry ban is "uncommon and reserved for the most egregious cases." That's a direct quote from their pretrial memorandum at page 49.

But this is not the type of case in which the FTC or the states have pursued industry bans. For this Court to issue

an industry ban, we submit would simply constitute punishment, which is not the purpose of an equity court.

For that, your Honor, I can refer you to the Liu case, which was cited earlier by plaintiffs in the Supreme Court. *Liu v. SEC*, 140 S. Ct. 1936 at page 1945 (2020). The plaintiffs have cited a number of cases in their pretrial memorandum, some of those we saw this morning, maybe all of them, in which courts have issued industry bans. In every single one of those cases there was fraudulent conduct by the defendant. And there has been no fraud alleged here.

This is a civil rule-of-reason antitrust case. It's not about, we would humbly submit, whether the price increase was a wise decision and whether we agree or if the Court agrees with that decision. This is about antitrust. They have not shown why in this particular case, on these facts, with these allegations, the defendant should be banned from an industry for the remainder of his life. The cases where they have done that have been fraud cases akin to criminal cases. Whatever else Mr. Shkreli has done, which I would submit is not relevant to what he did in this case, there is no justification for an industry ban in this particular case.

I don't want to discuss those cases that they have cited in any detail, but I would mention one that is worth mentioning. It's a case called *FTC v. Ross*, 897 F.Supp.2d 369. It's from the District of Maryland in 2012. The Court in *Ross*

specifically declined to issue an industry ban. Instead, the defendant was permitted to continue working in the industry with conduct restrictions. This was so despite that the defendant's fraudulent marketing scheme generated large sums of money and resulted in the filing of over 3,000 consumer complaints with the FTC.

Plaintiffs point to no case where the government has sought or the Court has imposed an industry ban in an antitrust case without any allegations of fraud. The Court should not take the apparently unprecedented step of imposing an industry ban in an antitrust case when conduct restrictions would be sufficient to restrain and prevent the challenged conduct from recurring.

THE COURT: What conduct restrictions do you recommend?

MR. CASEY: Your Honor, I don't think you should impose any. Our position is you should not. We don't think you should find liability. But if the Court were to find liability, restrictions that are tailored to the allegations in the complaint: Exclusive supply agreements, restricted distribution agreements, data blocking agreements. Those are the allegations in the complaint. And what they are doing now is going well beyond those.

I know the Court has lots of criminal cases. It's as if the defendant was ready to plead to every count of the

indictment but yet that's not enough. There has got to be some extra sanction imposed on the defendant.

In this case the FTC and the states are enforcing the antitrust laws and they do a very good job of it. I used to be at the FTC many years ago. I respect what they do. But what they do is, they are there to protect the market and to make sure that this kind of conduct -- again, I don't agree with their theory of the case, but I respect their right to bring the case. They bring the case. They get relief and the market -- they fix the market harm. In my view, that's what they should be doing instead of expelling an individual from an industry for the rest of his life. I don't think that's appropriate here, particularly in an equity court. I don't think there has been anything presented by them other than -- obviously, there has been a lot of negative publicity associated with Mr. Shkreli. He has acknowledged that. He takes responsibility for that. He did in his affidavit.

THE COURT: He didn't take responsibility for violating the antitrust laws.

MR. CASEY: Correct.

THE COURT: He has not admitted liability here.

MR. CASEY: He has not, your Honor. We are defending the case.

THE COURT: When you say he took responsibility, he admitted that he's the one who set the price for the drug, for

Daraprim. He admitted he set it at 750. He is not denying he said he should have set it higher. I'm not quite sure what you are saying, he admitted.

MR. CASEY: I didn't mean to suggest that he's admitting the conduct.

THE COURT: OK.

MR. CASEY: What I'm saying is, from the tenor, I will say, of the discussion about what their relief should be, it seems like it's a little bit beyond what they have charged in the complaint and what they should be seeking. That is my view. I would submit to the Court that whatever the Court does -- and I respect that this is the Court's decision. You have discretion to do it. But my only point is, this is an equity court and the Court should find an equitable resolution, if the Court finds liability, that advances the legitimate law enforcement purposes of the plaintiffs. I don't know that they have made a case, at least I haven't heard it made, for why they would need to ban Mr. Shkreli from this industry for the rest of his life.

THE COURT: Is it or is it not relevant, from your point of view, for me to consider that he was the author of the strategy?

MR. CASEY: Your Honor, I don't know that I would necessarily agree -- it depends on what you mean by author, but certainly there is record evidence to support the fact --

THE COURT: No. I'm sorry. Let me put my question more directly. If I find he is liable for a violation of the antitrust laws and am now considering what kind of injunctive relief is appropriate, which is what I think you're addressing now.

MR. CASEY: Yes.

THE COURT: On the assumption that I have found him liable and have turned to the issue of formulating injunctive relief, is it -- in your view, should I find it to be true that I consider, in shaping the injunctive relief, that I have found he is the author of the anticompetitive strategy?

MR. CASEY: I think that's a valid consideration for the Court to make.

THE COURT: Would it be relevant, from your point of view, as a legal matter, for me to consider that it was a strategy, again, directed to the pharmaceutical industry and the role that the pharmaceutical industry plays in providing life-saving remedies to the public?

MR. CASEY: Certainly. That's certainly a consideration that's appropriate.

THE COURT: Would it be relevant for me to consider in this decision making that the specific drug that's at the heart of this is in fact a life-saving drug for which the decision about its administration must be made generally within 24 hours of symptoms?

MR. CASEY: Well, certainly, your Honor, that's something you could consider.

My point only, your Honor, is that you have to fashion and mold the relief to stop this from occurring again. I think that's an appropriate role for the Court. But a narrowly tailored injunction for a reasonable period of time would be an appropriate resolution rather than a ban. I don't know why they need a ban in this case. They have said there is an enforcement problem with something less than a ban. I am not sure I understand that. But I just ask the Court to consider that, what is appropriate and necessary, again, given that the issue here is whether there has been a violation of the antitrust laws and whether the Court needs to put in place an injunction to prevent that from happening again. That's I think the role of the Court. I respect the Court's discretion to come up with an appropriate injunction, if the Court decides to do that.

In terms of equitable monetary relief, your Honor, the *Liu* case from the Supreme Court says that disgorgement should not be a joint and several remedy. In *Liu*, the Supreme Court said the rule against joint and several liability for profits that have accrued to another appears throughout equity cases awarding profits. That's in the *Liu* case, 140 S. Ct. at page 1945. In other words, allowing joint and several liability "runs against the rule to not impose joint liability in favor

of holding defendants liable to account for such profits only as have accrued to themselves."

Liu also held that the amount of disgorgement must be limited to profits the defendant took from the alleged scheme. Here, the plaintiffs have failed to meet their burden to prove that Mr. Shkreli profited at all from Vyera sales of Daraprim. Mr. Shkreli testified in his written direct testimony that he invested approximately $18 million into Vyera, and plaintiffs have not rebutted this testimony.

The only asset Mr. Shkreli has from Vyera is his Vyera stock. He took no salary from the company. The plaintiffs have not proven the value of that stock. Professor Hemphill's calculation is flawed because even if the Court is inclined to hold Mr. Shkreli jointly and severally liable for Vyera's profits from Daraprim, the plaintiff has failed to show that those profits should be in the range of 53 to $64.6 million, as Professor Hemphill claims.

Professor Hemphill admitted on cross-examination that in performing his calculation he did not take into account the numerous business decisions that the generic companies made that I have talked about here today that contributed to their delay in entering the market. Therefore, the assumptions on which his excess profits model is based are flawed.

Your Honor, I just wanted to mention a few things about Mr. Shkreli and his future plans. I know it was

referenced in plaintiffs' presentation, and he addresses it in his affidavit.

Again, the Court has the discretion to decide, if the Court finds him liable, what the appropriate relief is. I will just say this. He does hope to change the public's perception of him following his release from prison and his return to civilian life. He said in his written direct testimony at page 83 that he hopes to "continue playing a role in the discovery of cures and treatments for rare and life-threatening diseases."

In conclusion, your Honor, we would ask that the Court find that Mr. Shkreli is not liable for any of the counts in the amended complaint. In the alternative, should the Court disagree, we ask the Court to impose relief that is narrowly tailored to the allegations of the amended complaint, such as an injunction to not engage in the alleged conduct for a reasonable period of time and to deny any monetary relief. Thank you very much, your Honor.

THE COURT: Thank you.

Counsel, I leave it to you as to whether we take a break, a short break, a luncheon recess, or no break at all. Whatever is your choice.

MR. MEIER: Your Honor, we think we would benefit from taking a break, either a short break and come back, or a lunch break. They are telling me short break on our side.

THE COURT: Why don't counsel consult, since it affects all of you, just off the record here with each other.

MR. MEIER: Your Honor, I think the parties agree to a 15-minute break and then we come back and wrap it up.

THE COURT: Great. Thanks.

(Recess)

MS. McFARLANE: Your Honor, may I briefly be heard on remedy?

THE COURT: Certainly.

MS. McFARLANE: Thank you.

Your Honor, I'll be very brief. New York Executive Law 6312 is a remedial statute, not a penal statute. There is no distinction in the statute between remedies for fraudulent conduct and otherwise illegal conduct. The anticompetitive conduct in this case is at least as egregious as the fraudulent conduct at issue in our cited cases.

(Continued on next page)

MS. McFARLANE: (Continuing) Whether a ban is appropriate in equity and whether joint and several liability is appropriate in equity is based on your Honor's fact-finding about Mr. Shkreli's conduct and culpability.

Mr. Casey was right — enforcers aim to protect the markets. And the only way to protect the market here is to keep Mr. Shkreli out of the market.

Thank you, your Honor.

THE COURT: So, counsel, that's it for the reply?

MS. McFARLANE: That's it.

THE COURT: That's fine, that's fine.

Okay. I think we're done. I will spend some time taking my pen to my draft and taking into account all the hard work counsel have expended during this trial to educate me. I thank you, and I wish everyone a happy holiday season.

Thank you.

(Adjourned)